

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN,
and IRBESARTAN PRODUCTS

CIVIL ACTION NUMBER:

1:19-md-02875-RMB-SAK

LIABILITY LITIGATION

**Case Management Conference/
Status Conference**

Mitchell H. Cohen Building & U.S. Courthouse
4th and Cooper Streets
Camden, New Jersey 08101
Thursday, October 10, 2024
Commencing at 1:02 p.m.

B E F O R E:

THE HONORABLE RENÉE MARIE BUMB, CHIEF
UNITED STATES DISTRICT JUDGE, and THE
HONORABLE THOMAS I. VANASKIE (RET.)
SPECIAL MASTER

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(Appearances continued onto next page)

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Robert B. Kugler (Ret.)

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1 (PROCEEDINGS held in open court before the Honorable
2 Renée Marie Bumb, Chief U.S. District Judge, and The Honorable
3 Thomas I. Vanaskie (Ret.) Special Master, at 1:02 p.m. as
4 follows:)

5 THE COURTROOM DEPUTY: All rise.

6 CHIEF JUDGE BUMB: Good afternoon.

7 MR. SLATER: Good afternoon, Judge.

8 MS. ALLON: Good afternoon.

9 MS. LOCKARD: Good afternoon.

10 JUDGE VANASKIE: Good afternoon.

11 CHIEF JUDGE BUMB: You can all have a seat. Thank
12 you.

13 Okay. Good to have you all here. Thank you all for
14 being here. So let me start with appearances. We're in the
15 valsartan matter. We'll start with the appearances.

16 MR. SLATER: Good afternoon, Your Honor. Adam Slater
17 on behalf of the plaintiffs.

18 CHIEF JUDGE BUMB: Good afternoon.

19 MR. HONIK: Good afternoon, Your Honor. Ruben Honik
20 for plaintiff.

21 CHIEF JUDGE BUMB: Afternoon.

22 MR. NIGH: Good afternoon, Your Honor. Daniel Nigh
23 for the plaintiffs.

24 MS. WHITELEY: Good afternoon, Your Honor. Conlee
25 Whiteley on behalf of plaintiffs.

1 CHIEF JUDGE BUMB: Okay. That's it for the
2 plaintiffs; good afternoon.

3 Okay. For the defendants.

4 MS. ALLON: Good afternoon, Your Honor. Devora Allon
5 from Kirkland & Ellis for Torrent.

6 CHIEF JUDGE BUMB: Afternoon.

7 MS. BRANCATO: Good afternoon. Alexia Brancato from
8 Kirkland, also for Torrent.

9 MR. OSTFELD: Greg Ostfeld from Greenberg Traurig for
10 Teva.

11 MS. LOCKARD: Victoria Lockard, Greenberg Traurig,
12 for Teva.

13 MS. DAVIDSON: Jessica Davidson, Skadden, Arps, for
14 the ZHP Defendants.

15 CHIEF JUDGE BUMB: Okay. All right. Good afternoon.

16 All right. So I'm happy to see you all here. To be
17 honest, I'm not sure where I want to start so we're just going
18 to have a conversation about it.

19 I have spent a significant amount of time really
20 trying to get a handle on the case. And what I keep coming
21 back to is, I think the plaintiffs and the defendants are
22 trying two different cases. And I keep coming back to that.
23 The more I ask for submissions, the more I become convinced of
24 it, because I just think there's a lot of argument that's
25 getting mixed in with evidence. And so I'm hoping that we can

1 have a really robust conversation so I can figure it out and be
2 comfortable with moving forward. Because if I don't have that
3 comfort level, I'm not moving forward; I mean, I just can't.

4 So I guess I'm going to start with you, Mr. Slater,
5 and Mr. Honik, or whoever wants to answer my question. And I
6 will say that I have read and reread Judge Rosenberg's Opinion
7 in the *Zantac* matter, which I have found to be very
8 instructive. I've read it many times. I sort of feel a little
9 bit like she felt, like she continued to flesh out the case and
10 flesh out the case.

11 So I guess my first question is, Mr. Slater, are you
12 trying a worthless, one word, or a worth less, two word, case?
13 That's my first question.

14 MR. SLATER: Our position is that -- and I think
15 we're focusing on the warranty claim. We talked about that.

16 CHIEF JUDGE BUMB: I only want to focus on the
17 warranty claim, because that has what's consumed all of our
18 energies right now, but, yes.

19 MR. SLATER: Okay. Because the warranty claim values
20 the product at the time of sale, our position is that because
21 of the status of the product being contaminated as it was, that
22 there was no value to that product because nobody would buy it
23 knowing the contamination existed, and it was not sellable in
24 that form.

25 CHIEF JUDGE BUMB: Okay.

1 MR. SLATER: And the defendants have agreed that it
2 should not have been sold like that. I think -- so our
3 position is there was no value.

4 Taking your rulings into account, however, my
5 understanding is that your ruling is, that may be so. And we
6 are not arguing another world. We're saying in the world where
7 they were actually sold, our position is they shouldn't have
8 been and they didn't have value for the reasons I said; but
9 your ruling is, that may be so, but they were sold. And in the
10 real world people bought them and it helped them from a medical
11 standpoint. Shouldn't that be factored in? Shouldn't the
12 defendant be allowed to say, it may be that we shouldn't have
13 sold it, but we did and you got value anyway?

14 And in terms of valuing the drug, even though the
15 risk may not have been acceptable to sell it, it was sold and
16 you got value, so the defendants are allowed to say, well, the
17 plaintiffs didn't get no value, they got some value, because
18 they got efficacy.

19 CHIEF JUDGE BUMB: And your response to that is?

20 MR. SLATER: Our response is that it's a jury
21 question. Your Honor has framed it as a jury question. So our
22 response is, we understand that that's where the trial is going
23 so, therefore, we'll make our arguments.

24 CHIEF JUDGE BUMB: What's your argument?

25 MR. SLATER: In terms of why there's no value?

1 CHIEF JUDGE BUMB: Yes.

2 MR. SLATER: Again, because the product was
3 contaminated in such a way with what we know was in it.
4 Everybody agrees it could not have been sold or should not have
5 been sold. So, therefore, based on the warranty law, there was
6 no value to that, because --

7 CHIEF JUDGE BUMB: You can't make that argument.
8 That's argument. That's what I'm -- this is what I'm
9 struggling with.

10 MR. SLATER: Well -- oh, I'm sorry.

11 CHIEF JUDGE BUMB: That's argument. That is an
12 argument. You can't argue to the jury let's pretend the facts
13 don't apply in this case and let's just pretend that these
14 should never have been sold from the first place. You can't
15 make that argument.

16 MR. SLATER: I'm glad you asked me that, because
17 we're not -- we're not saying it didn't happen.

18 CHIEF JUDGE BUMB: Right.

19 MR. SLATER: What we're saying is it shouldn't have
20 happened, okay. And we're saying that as a matter of how the
21 law applies to these drugs, it never should have been sold.
22 And we also argue that it may -- this is not an argument. This
23 is the evidence. And our regulatory expert, Dr. Plunkett, can
24 frame this.

25 CHIEF JUDGE BUMB: What's the -- tell me the

1 evidence, because this is what I hear the plaintiff saying, and
2 I don't think it's a permissible argument.

3 I keep hearing the -- this is how I hear the
4 plaintiff presenting it to the jury: It's so because we say
5 it's so. It's so because once the FDA recalled the drug, it is
6 *ipse dixit* evidence that it shouldn't have been sold from day
7 one and, therefore, since it shouldn't have been sold from day
8 one, it doesn't have any value. And Judge Rosenberg rejected
9 that position. And I think that her reasoning is very solid.

10 And so there had to be some value at the time of sale
11 because it was sold. The plaintiffs benefited from it for a
12 period of years until there was a recall.

13 And the other thing that I think has not been focused
14 on is that there is a big disconnect between the cases that
15 talk about sales post-recall versus sales pre-recall. And I
16 think that -- and, again, Judge Rosenberg talked about it, the
17 cases talked about it, I brought it up in my letter order to
18 the parties. I think we have to be very careful that when we
19 argue to a jury that the drug had no value, those cases are the
20 drug in post-recall.

21 I see your colleague shaking his head, but tell me a
22 case where it's not.

23 MR. SLATER: Okay. I think the *Debernardis*, I think
24 that's the name of the case, the Eleventh Circuit Court of
25 Appeals case --

1 CHIEF JUDGE BUMB: Unique on its facts, very unique
2 on its facts.

3 MR. SLATER: Similar to our facts, though.

4 CHIEF JUDGE BUMB: No, not at all.

5 MR. SLATER: Because it was a later finding for
6 products that had been sold and provided value to people for
7 years.

8 CHIEF JUDGE BUMB: And there was a recall, and they
9 should not have sold them post-recall.

10 MR. SLATER: But they were given damages, and they
11 were allowed to ask for the refund going back to the beginning.

12 CHIEF JUDGE BUMB: But they didn't argue to the jury
13 that they had no value because they should never have been
14 sold.

15 MR. SLATER: I think that is what they argued, Your
16 Honor.

17 CHIEF JUDGE BUMB: No. And not to mention that that
18 was on a motion to dismiss on top of it. So I think you got a
19 problem there.

20 MR. SLATER: Well, I mean --

21 CHIEF JUDGE BUMB: That's a motion to dismiss.

22 So let me tell you why that's important, because on a
23 motion to dismiss, I think it's very -- here's the thing, is
24 that, again, I keep going back to sugar pills. If at the end
25 of the day the recall was because these were sugar pills which

1 had no value, then I think it's a plausible argument because I
2 think it can be supported by evidence that they had no value,
3 zero value because they were sugar pills.

4 That's why the facts matter here. And, you know, as
5 I've thought about the plaintiffs' argument over and over
6 again, would you be standing before me making the same
7 argument, let's pretend, if at the time of the sale the
8 warranty was we are going to be providing red valsartan pills
9 and they turn out they're green?

10 MR. SLATER: No, we wouldn't, because that --

11 CHIEF JUDGE BUMB: Because?

12 MR. SLATER: Because that would not be, from our
13 perspective, material enough to support the argument that we're
14 going to make.

15 CHIEF JUDGE BUMB: Exactly.

16 MR. SLATER: But the materiality here is patent. And
17 you asked about the facts that we are going to establish, so I
18 think it's very important to --

19 CHIEF JUDGE BUMB: How do you -- let's stick with
20 materiality because I think that's an important word. How do
21 you get to material or materiality without causation?

22 MR. SLATER: The materiality is established by the
23 fact that the pills -- that the contamination with these
24 impurities --

25 CHIEF JUDGE BUMB: Yes.

1 MR. SLATER: -- rendered the products, in terms of
2 what was supposed to happen, as not what they were said to be.
3 What they were sold as was valsartan USP, the approved, valid,
4 consistent with the compendium valsartan.

5 CHIEF JUDGE BUMB: Let me change the facts.

6 There's a little speck of flour in them, FDA recalls
7 them later because, you know, drugs shouldn't have a little
8 speck of flour in them. Your argument?

9 MR. SLATER: I wouldn't be bringing that case.

10 CHIEF JUDGE BUMB: Your argument?

11 MR. SLATER: My argument is that the materiality of
12 that is -- we're not talking about a health risk, I assume, in
13 your hypothetical. There's no risk to health. That's not
14 something that you have years of regulatory guidances
15 precluding it, where there's analysis by the ICH Guidelines and
16 the FDA saying genotoxic probable human carcinogens are treated
17 differently than all other impurities and there's special
18 regulations for those. Flour doesn't fall into that category.
19 So the --

20 CHIEF JUDGE BUMB: So I think you're talking yourself
21 into the issue that I'm very concerned about.

22 I think that what the plaintiff is trying to do is to
23 have it both ways, is to stand up before this jury and say:
24 "These drugs should never have been sold, period. They have no
25 value."

1 The plaintiffs want to phrase it in terms of a
2 regulatory risk. I see no difference between a regulatory risk
3 and a biological risk, but we'll get there. Because I think it
4 then leaves a jury, you know, this elephant in the room with
5 risk of what, without mentioning the word "cancer," and then
6 tying the defendants' hands by not being allowed to prove that
7 it does not cause cancer.

8 MR. SLATER: Well --

9 CHIEF JUDGE BUMB: And I don't think -- I think that
10 deprives the defendants of their day in court.

11 MR. SLATER: I don't agree, and I'll tell you why.
12 First of all, there's a lot that you're obviously putting
13 out --

14 CHIEF JUDGE BUMB: Been thinking about, yes.

15 MR. SLATER: It seems like for a few minutes, so...

16 CHIEF JUDGE BUMB: I don't see this case much
17 different than the *Zantac* case; I don't.

18 MR. SLATER: It's a very different case than *Zantac*.

19 CHIEF JUDGE BUMB: I don't see it.

20 MR. SLATER: And I'll tell you why.

21 CHIEF JUDGE BUMB: Well, it's a standing issue and
22 all of that, but I don't see this much different.

23 MR. SLATER: It's very different, because in this
24 case -- I mean, if we want to get down into why this is
25 different, in our case, and it's very important to remember,

1 originally these drugs were a branded drug called Diovan
2 manufactured by what's called the tributyltin process. That
3 was the branded approved, FDA-approved manufacturing process.
4 When it came off patent, ZHP said, okay, we're going to copy
5 that and we're going to now manufacture it and sell it a lot
6 cheaper.

7 And then what they did is they changed the process in
8 2011 and 2012, and that is the watershed moment in this case.
9 They changed the process so they could make more money than
10 they could make by using the FDA-approved process that went
11 through clinical studies and was evaluated through the clinical
12 studies.

13 And what they failed to do is they failed to do
14 proper change control and proper risk assessment before they
15 ever started selling the zinc chloride or TEA with sodium
16 nitrite quenching pills.

17 You don't have any of that in the *Zantac* case. What
18 you have in *Zantac* is it turned out that because of the way the
19 product was manufactured after it went out the door --

20 CHIEF JUDGE BUMB: No; because it sat on the shelf
21 for a while or whatever, it produced, you know, NDMA.

22 MR. SLATER: NDMA.

23 CHIEF JUDGE BUMB: Yeah.

24 MR. SLATER: It's a completely different situation.

25 CHIEF JUDGE BUMB: No.

1 MR. SLATER: Because this is a process impurity that
2 was created in the factory on the manufacturing line when it
3 was actually manufactured. And that's how it was sold with
4 this impurity in it.

5 And, again, it was from the very beginning, because
6 of their decision to change the manufacturing process in a way
7 that violated the rules that say you have to do the proper risk
8 assessment and change control process. So it's very different
9 factually from *Zantac*.

10 And then what happens is, you're asking what are the
11 facts that get us to say there's no value, again, we're talking
12 the warranty claim here. A person walks up to the cash
13 register and says I'd like valsartan, here's my prescription.
14 They then -- the formulary list for this person on their
15 insurance company looks and says, okay, they can have this,
16 this and this. And every one of them says valsartan USP.
17 That's the warranty. If that warranty isn't there, it never
18 gets sold by -- nobody -- the retailers have said they wouldn't
19 have sold it.

20 CHIEF JUDGE BUMB: It's valsartan with a contaminant.

21 MR. SLATER: Well, it is.

22 CHIEF JUDGE BUMB: Why do you keep trying to dress it
23 up as something that it wasn't? It was valsartan but with a
24 contaminant.

25 MR. SLATER: But what's more important is -- or maybe

1 it's just the flip-side, but I think it's important to say it
2 this way, it wasn't what they said it was.

3 CHIEF JUDGE BUMB: I know. I understand all of that.
4 But that doesn't give you the right, you, the plaintiffs, the
5 right to say to the jury that just because it wasn't what they
6 said it was, we get -- we get a full refund because of the
7 recall. It should never have been sold, period.

8 MR. SLATER: Well, that's what --

9 CHIEF JUDGE BUMB: No. And I --

10 MR. SLATER: That's the law of -- that's the law of
11 express warranty, Judge.

12 CHIEF JUDGE BUMB: No. It's --

13 MR. SLATER: That is the law.

14 CHIEF JUDGE BUMB: Okay.

15 MR. SLATER: I mean, and I just want to say, I
16 understand that you want this to be fair, but the defendants
17 sold these drugs, misrepresented that they were USP Orange Book
18 compliant valsartan.

19 CHIEF JUDGE BUMB: So then prove to the jury that you
20 didn't get the "benefit of the bargain." But do not stand up
21 before the jury and say: "FDA recalled them so we should have
22 gotten -- we should have gotten a full refund."

23 MR. SLATER: Well, I mean, there's --

24 CHIEF JUDGE BUMB: You've got to be able to -- this
25 is what the "benefit of the bargain" is. You've got to be able

1 to introduce evidence to the jury as to what the value of these
2 drugs was, i.e., were they efficacious or weren't they, and the
3 defendants will do differently.

4 And, you know, I think the other thing that we have
5 to be very careful about is, we can't conflate liability with
6 damages, okay. And that's what I think the plaintiff is
7 continuing to conflate, which is the plaintiff will get up and
8 say, "Were these drugs adulterated?" You'll prove they were
9 adulterated, whether they were adulterated or they weren't.
10 You'll then prove damages. What are the amount of the damages?
11 But what you can't argue to the jury is: "They had no value
12 because the FDA recalled them."

13 MR. SLATER: We're saying --

14 CHIEF JUDGE BUMB: You can't prove -- you can't argue
15 that to the jury, just like Conti, whose testimony I found to
16 be unreliable.

17 MR. SLATER: We're not saying that that is all there
18 is to it. What we're saying is we're -- we are not -- again,
19 we're in the real world where when people went to the cash
20 register and they bought this, a warranty was made. And if
21 that warranty had not been made, they would not have been
22 purchased. Nobody would have purchased those drugs because
23 they couldn't, as a matter of law.

24 CHIEF JUDGE BUMB: You can't make that argument to
25 the jury.

1 MR. SLATER: But that's the law, Judge.

2 CHIEF JUDGE BUMB: No, it's not.

3 MR. SLATER: And -- and the other --

4 CHIEF JUDGE BUMB: That's argument.

5 MR. SLATER: That's the evidence and the admissions
6 from every defense witness who was asked the question; that
7 once they knew there was NDMA in it, they knew this could never
8 be sold.

9 CHIEF JUDGE BUMB: But that's a different case.
10 These are not the facts of this case. You want --

11 MR. SLATER: So they get a pass?

12 CHIEF JUDGE BUMB: I don't know.

13 MR. SLATER: Because they got away with selling
14 the -- this is my problem, Judge: They sold the pills and
15 they're saying, well, nobody caught on so, you know what --

16 CHIEF JUDGE BUMB: That may go -- that may go to your
17 fraud claim. But I don't see how it goes to your express
18 warranty claim.

19 MR. SLATER: And then they say -- and it turns out in
20 hindsight, even though we measure the damages at the cash
21 register, and that's the law, we've established that, our brief
22 I think was very compelling on that, that's when you measure
23 damages on the warranty claim is when the person buys it, do
24 they get the benefit of their bargain at the time of purchase.

25 CHIEF JUDGE BUMB: That's liability. Talk about

1 damages.

2 MR. SLATER: It's also damages, because if you don't
3 get the benefit of the bargain, under warranty law you're
4 allowed -- you are entitled to get your money back.

5 What you're letting them do --

6 CHIEF JUDGE BUMB: No. But you just told me a few
7 moments ago that if it had flour in it, you're not getting the
8 benefit of your warranty because nobody would go to the
9 counter, presumably, and say, oh, can you give me some pills
10 with a little speck of flour in them.

11 MR. SLATER: Those hypotheticals don't apply to this
12 case.

13 CHIEF JUDGE BUMB: Why?

14 MR. SLATER: Because it's not this case. You're
15 taking our case and you're watering it down with a hypothetical
16 that doesn't apply, Judge.

17 CHIEF JUDGE BUMB: No. I'm just trying to show you
18 why the plaintiffs are wrong on the law.

19 MR. SLATER: We have -- we're -- under warranty law,
20 this is -- and let me finish what I'm saying here. You're
21 saying to us, okay, how can you say there's no value. We have
22 the law that says this could not have been sold if they didn't
23 give this false warranty.

24 If they said it's valsartan but it's not USP, it
25 doesn't get on the formulary, it's, therefore, not approved by

1 the TPP, by the insurance company, and the retailer will not
2 sell it. That is the law. That is the facts. It's agreed by
3 everybody.

4 CHIEF JUDGE BUMB: I know. I know, but Mr. Slater --

5 MR. SLATER: So what they're doing -- I want to
6 finish with the efficacy issue, Your Honor, because I know that
7 that's what you're concerned about.

8 We're allowed to make our argument that there's no
9 value because they should never have sold it; no one would ever
10 have bought it if they knew.

11 CHIEF JUDGE BUMB: I disagree.

12 MR. SLATER: So they then have -- you're letting
13 them, though, say even though you valued the product at the
14 time of sale, you're saying they can go back, though, years
15 later and say, you know what, even though we shouldn't have
16 sold it, they got some benefit from the therapeutic value so
17 there's value so it shouldn't be -- you can't take away all of
18 the -- you can't give a full refund because there was value.
19 And they're going to make that argument to the jury. And
20 that's where the horserace will be with the jury.

21 And Judge Kugler always said that -- and I know you
22 know that -- this case is about the value. The jury has to
23 decide what was the value.

24 We don't agree that they should be allowed to make
25 that argument, but they're doing it, and we're not griping

1 about it, we're ready to deal with it, and the jury will decide
2 who's right and who's wrong based on the facts. This is not an
3 argument. This is the facts and the evidence, which is their
4 admissions. They could not sell it. They could not sell this
5 product.

6 CHIEF JUDGE BUMB: Had they known that it contained a
7 contaminant.

8 MR. SLATER: Well --

9 CHIEF JUDGE BUMB: They're not disputing that. But
10 what evidence are you going to introduce to a jury that this
11 should never have been sold in the first place and, therefore,
12 it's a zero value?

13 MR. SLATER: Well, in terms of its --

14 CHIEF JUDGE BUMB: That's strict liability to me.

15 MR. SLATER: And we gave you the law; that warranty
16 law is akin to strict liability.

17 CHIEF JUDGE BUMB: And I didn't -- and I don't think
18 that that was --

19 MR. SLATER: And they've given you no cases that say
20 to the contrary because that's what it is. Warranty law is
21 very straightforward and very simple. They represented this
22 was approved by the FDA to be sold, and it wasn't.

23 And the fact that they didn't know about it doesn't
24 give them a break. You're not allowed to be ignorant of what's
25 in your pills.

1 CHIEF JUDGE BUMB: Let me read from Judge Rosenberg's
2 Opinion the following and then I'll have you respond to it.

3 So this is what -- gearing up to the adulteration
4 theory, she writes: "The plaintiffs' adulteration theory of
5 standing is not viable because it improperly relies on the
6 FDA's ADI. The FDA established the ADI for NDMA in ranitidine
7 around 2019. The plaintiffs' claim that ranitidine was
8 adulterated as determined by Congress because it was sold with
9 amounts of NDMA higher than level permitted by Congress," et
10 cetera.

11 "In other words, it [sic] was adulterated because it
12 contained levels exceeding the FDA's ADI; since it was
13 adulterated, it was worthless; and since ranitidine was
14 worthless, the plaintiffs suffered an economic injury-in-fact
15 when they purchased it for a value greater than zero, without
16 knowing that it contained NDMA."

17 She then goes on to rule -- she contrasts the
18 *Debernardis* case and says, "a plaintiff does not have standing
19 to sue a defendant merely because of buyer's remorse. The
20 Third Circuit concluded that a plaintiff lacked standing to sue
21 L'Oreal for its failure to disclose that there were trace
22 amounts of lead found in its lipstick in part because the
23 plaintiff's subjective allegation that the trace amounts of
24 lead in the lipstick are unacceptable to her did not constitute
25 injury-in-fact."

1 Here is the key language, I believe.

2 "Without evidence that a product was illegal to
3 sell" -- that doesn't apply here -- "harmful, or overpriced, a
4 plaintiff does not suffer injury from purchasing a product and
5 later wishing that he or she had not done so."

6 And she goes on and finds that the plaintiffs were
7 unable to put forward reliable evidence to prove that
8 ranitidine was unsafe.

9 So I don't -- I don't see a significant distinction
10 here; I just simply don't.

11 MR. SLATER: Your Honor, my response is this: First
12 of all, I'm told -- I'm asking my team for the cite.

13 CHIEF JUDGE BUMB: Yeah.

14 MR. SLATER: That she was reversed on standing by the
15 Eleventh Circuit, so we'll have to see if that's correct.

16 CHIEF JUDGE BUMB: Okay.

17 MR. SLATER: I'm telling you this is what I'm
18 hearing, but I'm asking my team to find the citation to the
19 case from the Eleventh Circuit.

20 Number two, that -- she said if it was illegal to
21 sell, it was illegal to sell it.

22 CHIEF JUDGE BUMB: It's illegal to sell lead in
23 lipstick.

24 MR. SLATER: Ah. No. But there's not genotoxic
25 carcinogen guidelines that were applicable that during the time

1 this was sold -- see, we're not relying on the FDA limits that
2 came after the fact, because we're relying on the fact that
3 when this was being sold, none of the NDMA or NDEA was allowed,
4 zero was allowed unless they actually have identified it,
5 evaluated it and controlled for it and then went to the FDA and
6 said, look, this is how much is in here, we think it's safe,
7 we've done the risk assessment, let us sell it up to this
8 level.

9 During the time it was sold, none of that happened,
10 and during that time zero was allowed. And you're not going to
11 hear anybody say to the contrary in -- I mean, I guess anyone
12 can say whatever they want, but that was the law. And the law
13 said you couldn't sell it. So, A, it was illegal to sell.

14 The unacceptable risk was an unacceptable health
15 risk. We can talk about the general causation issue. I would
16 hope that our brief on Dr. Chodosh was compelling because he
17 made the argument more eloquently than I can ever --

18 CHIEF JUDGE BUMB: No. It raised more questions than
19 answers, quite frankly, it did.

20 MR. SLATER: Well, it raises --

21 CHIEF JUDGE BUMB: Was the case reversed on appeal?
22 That's not what I believe it was. I don't believe -- I don't
23 think that it --

24 MR. SLATER: I'm waiting to be told, but --

25 CHIEF JUDGE BUMB: I don't think it was.

1 MR. SLATER: So it was illegal to sell it. We have
2 that. And we don't rely on the later standards. And, by the
3 way, the later standards it still exceeded those levels that
4 came in in 2018 when the FDA --

5 CHIEF JUDGE BUMB: When you say it was illegal to
6 sell --

7 MR. SLATER: The FDA does not allow you to sell a
8 drug that's not in the approved form.

9 CHIEF JUDGE BUMB: I think we're talking in circles.
10 Can I hear from your adversaries? Because I don't want to have
11 you do all the...

12 MR. OSTFELD: Thank you, Your Honor.

13 Your Honor, I think you asked a very salient question
14 at the beginning, which is the distinction between a
15 worthlessness theory, one word, and a worth-less theory, two
16 words.

17 I think the challenge here is plaintiffs are very
18 clearly asserting a worthlessness theory.

19 CHIEF JUDGE BUMB: One word?

20 MR. OSTFELD: One word. And they have no evidence of
21 a worth-less theory. And that's not inherently disqualifying.
22 It's possible to have a worthlessness theory, one word, that
23 comports with the "benefit of the bargain" measure of damages.
24 But --

25 CHIEF JUDGE BUMB: How? But how do you get -- how

1 without going to the issue of causation?

2 MR. OSTFELD: With admissible evidence which does
3 have to go to the issue of causation, and it has to go to the
4 issue of efficacy. You have to show the value as received.

5 I think the parties, with all the case law we've put
6 out there, I actually don't think there's that much distance
7 between our respective cases on the question of what "benefit
8 of the bargain" means. It means the difference between the
9 value as warranted and the value as received.

10 CHIEF JUDGE BUMB: Right. And so but -- and I agree
11 with that, but it seems to me that the only thing that's left
12 is for the plaintiff to argue it should never have been sold,
13 therefore, there's zero value. And that's argument to me.

14 MR. OSTFELD: I agree, Your Honor. And I think
15 you've put your finger on the exact problem here. They're not
16 positing admissible evidence of the value as received. What
17 they are positing is an argument of the value as if it should
18 never have been sold.

19 CHIEF JUDGE BUMB: And that's not evidence.

20 MR. OSTFELD: That is not evidence. And, that is,
21 the essence of Professor Conti's approach, which you have
22 excluded, is essentially a policy argument and a moral argument
23 that it should be deemed valueless, because if we knew then
24 what we know now, it would not have been sold or could not have
25 been sold. But that's not evidence of the value received.

1 In the real world, as Mr. Slater indicated, value was
2 received. Patients received effective hypertension medication.
3 They took it for years. They received the antihypertensive
4 benefits. The third-party payor plaintiffs received the
5 benefit of their members receiving effective hypertension
6 medication.

7 So that, I think, is the problem. There isn't
8 admissible evidence on the worthlessness -- one word -- theory.

9 So what I think Mr. Slater is postulating as a backup
10 is, okay, we let the jury decide. The defendants will come in
11 and put in their evidence that the product was efficacious. He
12 still doesn't want general causation to come in. As
13 Ms. Lockard will discuss, if you come to the general causation
14 issue, we think it has to come in because you have to get into
15 whether the product was safe or not.

16 I'm sorry.

17 CHIEF JUDGE BUMB: Just wait one second because I'm
18 too distracted.

19 MR. OSTFELD: Okay. Meanwhile, Your Honor, I did --

20 CHIEF JUDGE BUMB: Go ahead. I'll let you talk,
21 confer.

22 MR. SLATER: I'm sorry, Judge.

23 CHIEF JUDGE BUMB: That's okay. If you want to
24 confer, go ahead; I just can't --

25 MR. SLATER: No, no. We won't do that again.

1 CHIEF JUDGE BUMB: That's okay. I'm just -- I'm hard
2 of hearing, so no worries.

3 MR. SLATER: I apologize. I have the same issue.
4 Sorry.

5 CHIEF JUDGE BUMB: Yeah. Mr. Ostfeld, go ahead.

6 MR. OSTFELD: So apologies, Your Honor. So where we
7 are is we have a case that the product was efficacious. We
8 have a case that the product was not dangerous, notwithstanding
9 the presence of NDMA impurities.

10 Plaintiffs would have their own general causation
11 evidence. There would certainly be a dispute to put in front
12 of the jury as to whether or not the NDMA impurity made
13 valsartan dangerous. I'm not aware of any evidence on the
14 plaintiffs' side that it was not efficacious.

15 So, regardless, what plaintiffs don't have is
16 admissible testimony on damages. And I think you drew a very
17 critical distinction between liability and damages. If --

18 CHIEF JUDGE BUMB: Well, and that was going to be my
19 question, then aren't we in summary judgment land? Because if
20 it's just strictly argument, shouldn't have been sold, zero
21 value, that's strictly argument.

22 And that's the -- you know, I remember when I first
23 was assigned to this case, and I posited the question to you
24 all, I don't know -- I don't know of anyone on this side of the
25 room that would stand up before the jury and say, yeah, it

1 should have been sold knowing what we know now. I don't -- I
2 can't imagine that they would be making that argument to the
3 jury. The fight is going to be when did they know it, et
4 cetera, et cetera, and that's the fight.

5 But I can't imagine the defendants standing before
6 the jury and saying, yeah, don't pay attention to what
7 Mr. Slater just told you because it was fine that we sold it
8 knowing what we know now. That's just not going to happen.

9 And so, I mean, so that's why it shows to me that
10 this is strictly argument, ladies and gentlemen, let's just
11 pretend that we are living a different case and you go back and
12 you decide and you give -- you give the drug zero value because
13 it should never have been sold, when for years it did what it
14 was supposed to do. And then it just raises the question of,
15 well, why shouldn't it have been sold? Well, it shouldn't have
16 been sold because there's this thing called -- which we really
17 can't tell you -- carcinogen.

18 And then they, the defendants, can't come forward and
19 say, well, don't worry about this carcinogen because it's not
20 really what you think it is.

21 I mean, it just -- the whole causation thing is
22 another problem.

23 MR. SLATER: Well --

24 CHIEF JUDGE BUMB: But let Mr. Ostfeld finish first.

25 MR. OSTFELD: Yes, Your Honor.

1 And I think you've also hit on an important
2 differentiation between what's going on in the Eleventh Circuit
3 with the *Debernardis* case, as well as the ongoing appeals of
4 the *Zantac* standing order. We're not at the standing stage
5 here. We're not at the motion-to-dismiss stage.

6 And the concurrence in the *Debernardis* case, Judge
7 Sutton's concurrence is very compelling and very significant on
8 this point, because Judge Sutton draws that exact distinction.
9 He says, "Saying that an allegation is sufficient to cross the
10 very low threshold for Article III standing is not the same
11 thing as saying even that you have liability, much less proving
12 up damages."

13 And he specifically drew the differentiator between
14 sufficient injury to plead standing and sufficient injury to
15 prove up damages at trial. And he said -- and in his case he
16 was talking about the summary judgment stage, at the summary
17 judgment stage, the plaintiffs are going to have to come
18 forward with evidence to show why it was worthless and how it
19 was worthless.

20 CHIEF JUDGE BUMB: And from what I can gather from
21 the record here, I think if I, you know, were to assess what
22 Judge Kugler was thinking at the time, this was at the
23 motion-to-dismiss stage. And so at summary judgment stage,
24 what he ruled was the plaintiffs will have to come forward and
25 show through admissible evidence that it had zero value.

1 And saying it had zero value because it should never
2 have been sold is strictly -- it's just argument revising
3 history. That's where I keep coming around. So I just don't
4 know how -- and that's what -- that's the problem I had with
5 Conti.

6 Conti was rendering an expert opinion about something
7 that I thought was very common sense, yeah, drugs that
8 shouldn't have been sold have no value. But that's because if
9 there's a recall, you shouldn't sell them and you should get no
10 value for them. They have no value if you're selling them.
11 And that was, I think, the *Blue Cross Blue Shield* case. I know
12 plaintiffs are disagreeing with my analysis of that. But --

13 MS. ALLON: Your Honor, could I just add one thing
14 before we go back to the -- or are you --

15 MR. OSTFELD: Please.

16 MS. ALLON: Before we go to the plaintiffs, just
17 about Judge Rosenberg, since I represent GSK in that case, she
18 has not been reversed, just so we're clear.

19 CHIEF JUDGE BUMB: Is it on appeal?

20 MS. ALLON: Yes.

21 CHIEF JUDGE BUMB: But it may never get -- didn't
22 they just settle yesterday?

23 MS. ALLON: They settled the state cases.

24 CHIEF JUDGE BUMB: Oh.

25 MS. ALLON: But not the MDL. And so that decision,

1 along with her 280-page decision finding that NDMA does not, in
2 fact, cause cancer, are up on appeal to the Eleventh Circuit.
3 The briefing is not even completed.

4 CHIEF JUDGE BUMB: Oh.

5 MS. ALLON: So there's been no reversal. And we
6 don't expect there to be a reversal.

7 CHIEF JUDGE BUMB: Yeah. I didn't -- I thought for
8 sure that it was still good law. But, okay, thank you.

9 MR. OSTFELD: Your Honor, I guess the final point
10 that I would like to make goes to Professor Conti. I agree
11 with Your Honor. I think what Professor Conti did,
12 essentially, was assign herself a regulator's role and say not
13 here is the value of these drugs as received, as received they
14 were worthless, she says we should treat them as worthless,
15 because in an alternative reality, knowing then what we know
16 now, they would not have been sold or could not have been sold.

17 CHIEF JUDGE BUMB: Yeah. And that's how I -- that's
18 how her testimony was. And I said, well, that's just -- those
19 facts do not fit my case.

20 MR. OSTFELD: So I do think the exclusion of
21 Professor Conti's opinion on that point does move us at least
22 closer to summary judgment territory. Certainly I can envision
23 a world where at the conclusion of plaintiffs' case we bring a
24 directed verdict because there is not evidence to put in front
25 of the jury on the quantification of plaintiffs' damages. I

1 don't want to predict what their case will be.

2 I will say as I stand here today, I do not know what
3 their evidence is that demonstrates that the product is worth
4 less, two words. They only had the worthless theory, and it
5 was only due to Professor Conti's excluded opinion. So I do
6 think this presents a challenge for plaintiffs at trial, but I
7 don't want to speak for what their evidence would be.

8 Your Honor, just to kind of lay the framework for the
9 other issues that Your Honor noted in your letter, Ms. Lockard
10 will be covering adulteration and general causation. Ms. Allon
11 will be covering the alternative drugs analysis, the Motion in
12 Limine 16. I'm here to speak to you about worthlessness and
13 the benefit-of-the-bargain theory. Unless you have other
14 questions for me, I think I've concluded what I wanted to say
15 on --

16 CHIEF JUDGE BUMB: Well, is it your position that as
17 to the -- well, "worthless" was Conti. But even if there were
18 a claim for worth less, two words, there's no evidence that the
19 plaintiffs have introduced?

20 MR. OSTFELD: So, Your Honor, it is our position that
21 there is no evidence -- there is no damages evidence on worth
22 less. I think they could put in evidence that on -- there
23 could be a clash on general cause if that were brought in as
24 part of the worth less inquiry. But they do not have a witness
25 who has "value," the diminution in value.

1 CHIEF JUDGE BUMB: What do you mean by "general
2 cause"?

3 MR. OSTFELD: So let me pose my own hypothetical if
4 it doesn't offend Your Honor.

5 In a world where plaintiffs had presented the type of
6 damages that courts accept on a worth less, two words, frame,
7 the analysis would be, the value as received was less than the
8 value as warranted because the safety characteristics were this
9 much less safe, or the efficacy characteristics were this much
10 less efficacious and, therefore, based on a -- perhaps a survey
11 design or some other study, we have determined that consumers
12 would pay X dollars less for the product.

13 So general cause certainly becomes part of the
14 analysis there because you have to know how much less safe the
15 product is.

16 I think they could put on a case on they believe the
17 product is less safe. We believe the product is not less safe.
18 There could be a clash on that. I'm not aware of any clash on
19 efficacy. But what's missing from their case, they do not have
20 anybody who can say, therefore, the product is worth X dollars
21 less.

22 The jury can't just be put out in the wilderness and
23 told you've heard the evidence on safety, you've heard the
24 evidence on efficacy, now you go figure out what it was worth.
25 There has to be testimony, admissible evidence from an expert

1 that tells them, gives them the ability to quantify damages
2 under the two-word "worth less" scenario. And it doesn't exist
3 in this case because plaintiffs made a strategic decision to go
4 all in on worthlessness, one word.

5 MS. ALLON: Right. I was just going to say, I think
6 Mr. Ostfeld got there. There's nothing to go to a jury on that
7 point, because Dr. Conti did one damage calculation, which is
8 full refund. And so if the plaintiffs are going to change
9 their theory of damages to diminution in value, there is
10 nothing to try in front of this jury. There is no evidence
11 that they have as to what their damages are in a
12 diminution-in-value theory. Dr. Conti didn't do it, and they
13 have no other expert to do it.

14 CHIEF JUDGE BUMB: Well, she tried to do it, but I --

15 MS. ALLON: No. She just did the full value. She
16 did worthless, not worth less.

17 CHIEF JUDGE BUMB: But she's not a biologist. She
18 wouldn't have been qualified to do that anyway.

19 MS. ALLON: Well, they would have had to have a
20 survey expert, and then she would have calculated -- my point
21 is, there's no damages numbers to put before a jury. So were
22 we here on summary judgment on diminution of value, worth less,
23 we would have to prevail because there is no evidence from the
24 plaintiffs in the record as to what their damages are under
25 that theory. We don't have to wait for a directed verdict.

1 There's no evidence. There's nothing to put in front of a jury
2 because they don't -- aren't pursuing that theory.

3 CHIEF JUDGE BUMB: Okay. Ms. Lockard, did you want
4 to say something? Or Ms. Davidson, I'm sorry. No?

5 MS. DAVIDSON: No. I think everything was said.

6 MR. SLATER: Okay. I want to take a little bit of a
7 step back to what's happening now.

8 We've been proceeding based on the rulings that have
9 been made in this case for five years. And Judge Kugler ruled
10 on the decisions that got us here. On the motion to dismiss he
11 actually ruled there is no value when you sell an adulterated
12 drug. I understand that was the motion to dismiss. On the
13 summary judgment motions, he denied our motion, and both sides'
14 motions. And he said the value is somewhere between zero and a
15 hundred percent, and that's going to be for the jury to decide.

16 CHIEF JUDGE BUMB: Based on admissible evidence,
17 that's true.

18 MR. SLATER: So --

19 CHIEF JUDGE BUMB: Based on admissible evidence, not
20 argument. That's true.

21 MR. SLATER: And he ruled that we had evidence that
22 was sufficient to go to the jury on that question.

23 So to now say we're going to change the rules on the
24 two-yard line or something and say, well, now -- I suppose Your
25 Honor could rule, look, I'm not going to let you say no value,

1 and you're going to have to say that it's less value, and we
2 would not be happy about that, we would preserve our rights,
3 but we would have to try the case under that basis.

4 How would we prove it? We would put in the same
5 evidence that we already were going to put in. We would put in
6 this is what was paid. If you find no -- if you found no
7 value, it would be this. But the Court has told you, you have
8 to find some value, so you can use these numbers, and you can
9 listen to what the defense said.

10 Remember, they have an unquantified value argument on
11 the defense side. They have Dr. Stiroh who says, well, there
12 is value because I'm relying on the people who say there was
13 efficacy, but I never calculated what it was and I don't have a
14 number for that. So she doesn't give any guidance to the jury
15 on that at all.

16 But the jury then looks at this and says, okay, this
17 is what was paid, this is what the plaintiffs say, this is what
18 the defense says, and the jury says we're going to -- and they
19 decide where they think in reason, based on the instructions of
20 how value is established, what the value was. That -- if Your
21 Honor wants to --

22 CHIEF JUDGE BUMB: Tell me the evidence the jury is
23 going to look at to determine value.

24 MR. SLATER: They're going to hear all the evidence
25 on our side of the fact that at the cash register --

1 CHIEF JUDGE BUMB: Yeah.

2 MR. SLATER: -- on the warranty claim, there was
3 no -- that you were not allowed to sell this, and it was
4 illegal to sell.

5 CHIEF JUDGE BUMB: They're not going to hear that.

6 MR. SLATER: Well, Judge --

7 CHIEF JUDGE BUMB: I'm not going to permit that.
8 That's argument.

9 MR. SLATER: It's not. It's the law.

10 CHIEF JUDGE BUMB: That is argument.

11 MR. SLATER: The law is that it was illegal to sell
12 these products.

13 And these -- you know, it's amazing that we're on the
14 defensive with these lawyers on the defense side putting us on
15 the defensive when these companies sold blood pressure pills
16 contaminated with genotoxins, and we're sitting here having to
17 explain why we should be allowed to recover in a warranty
18 case --

19 CHIEF JUDGE BUMB: Because --

20 MR. SLATER: -- where their own witnesses admit that
21 at the cash register if they hadn't represented it was
22 valsartan, falsely represented, it was valsartan USP, that was
23 a false representation, they could never have sold it. And
24 there's not one person in this room that's going to stand up
25 and say, yeah, we could have sold it.

1 And Your Honor asked, are they arguing it was okay to
2 sell it; nobody on the defense side is going to say it. That's
3 exactly what they want to argue. They want to say put aside
4 that the FDA found the risk was unacceptable and every pill
5 that was out there that people were ready to sell or take --
6 that were ready to sell had to be recalled, and nothing else
7 was ever sold after that moment when the FDA found out. They
8 put it in place, nobody could sell it. They want to relitigate
9 that. Your Honor ruled in July they could not relitigate the
10 FDA findings. And they now want to say don't worry about what
11 the FDA said. The risk really wasn't bad and it shouldn't have
12 been found unacceptable because it didn't hurt anybody.

13 And, by the way, let's just parenthetically put aside
14 the fact that there's been three studies done on valsartan
15 pills taken by people based on large insurance databases. The
16 Gomm study, the most recent study they came up with both found
17 increased risk of liver cancer statistically significant.

18 And the last study that they were arguing about to
19 Your Honor, they haven't mentioned it in a while, also found
20 melanoma.

21 The Pottegard study, we have all sorts of arguments
22 about why it didn't get to statistical significance, very
23 compelling.

24 So they're standing here acting like there's no
25 evidence it caused cancer. The only studies actually done on

1 valsartan pills found it causes cancer in people, liver cancer,
2 in two of the three studies. So --

3 CHIEF JUDGE BUMB: And that's the elephant in the
4 room you don't want the jury to hear about.

5 MR. SLATER: I don't know. I -- we filed a brief to
6 Your Honor. I'm starting to get a little exercise. I drank
7 coffee. No, I didn't actually. I'm joking.

8 What the defense wants to do is they want to say -- I
9 lost my train of thought trying to be funny. I'm sorry.

10 CHIEF JUDGE BUMB: Well, it's the elephant in the
11 room.

12 MR. SLATER: Oh, I know where, okay. So we've
13 submitted to Your Honor the way that courts deal with
14 situations like this, with an instruction. That instruction
15 that we've submitted hits the issue head on and tells the jury
16 what they're to consider and what they're not to consider.

17 The fact that there's an unreasonable carcinogenic
18 risk is a matter of fact and a matter of law. This is
19 evidence. It's not argument. It's the evidence and the facts
20 in the real world. And the defense wants to argue, well, you
21 know what, let's put that aside and let's put on Dr. Chodosh
22 who parenthetically said I'm not an expert on regulatory
23 standards, which are protective and more conservative to
24 protect the safety of people. I didn't even analyze that. I
25 analyzed biological causation of cancer, which is not an issue

1 in an economic loss case.

2 So they want to bring in an expert who admitted I
3 don't fit that case at all, I'm not qualified and I didn't even
4 evaluate that question. And they want to bring him in to say
5 well, you know what, the risk wasn't really that bad. Nobody's
6 actually going to get cancer from this. So putting that --
7 it's not an elephant in the room. It would be putting a wild
8 tiger in the room to start eating everybody. It doesn't
9 belong.

10 And the easy way to deal with it, the way the courts
11 do this every day, as Your Honor knows, is you give a limiting
12 instructions. You say you're going to hear all sorts of words
13 like "genotoxin," and you're going to hear about "probable
14 human carcinogen," and you're going to hear all this language
15 from the regulations, and that's the question. And those are
16 the standards that applied to whether you could sell this drug
17 because that's what NDMA and NDEA are.

18 What you're not deciding in this trial is whether
19 those pills with those amounts actually caused cancer in
20 anybody. Because the law and the facts are you weren't
21 supposed to sell it with that stuff in at all. And the defense
22 cannot dispute that. Nobody is going to dispute that. They
23 want to dispute it through the back door of general causation
24 where, as we pointed out in our brief, they already won a
25 motion to say we're not allowed to bring in the fact that

1 there's a whole bunch of people that are claiming they got
2 cancer from this and that we have strong evidence on. They
3 kept out cancer causation already, but now they want it to come
4 in also, so they want it both ways. We're not trying to have
5 it both ways. We want to live in the world of this is the law,
6 this is what they were allowed to do.

7 And at the cash register the fact that there was
8 efficacy, we are able to say in opening statement, you know,
9 the defense is going to tell you that at the cash register
10 there was value because this was going to control blood
11 pressure.

12 Well, in the real world, if they didn't represent
13 that it was what it was supposed to be but actually told the
14 truth and said, look, it's supposed to have five attributes,
15 but the thing about safety, purity and quality, it doesn't have
16 that, but it's still going to help you, what do you want to pay
17 for it?

18 Judge Kugler already precluded the expert. I think
19 it was Dr. Keller who wanted to say that, and that expert is
20 not allowed to testify. So they tried to back-door in through
21 Dr. Stiroh now. That's their argument. If Your Honor wants to
22 let them make that argument, let the jury decide well, all
23 right, you know what, we could say it had these two attributes,
24 it had the right ingredients, for the most part, and it had the
25 right strength to control blood pressure. It didn't have the

1 purity and the safety and the quality, and we're going to say
2 all right, it had 60 percent -- it had 40 percent of what it
3 was supposed to have but not the other 60 percent, so they can
4 value it based on that because that's what -- if they're
5 allowed to argue the efficacy, that's essentially on the
6 warranty claim, which, again, is the only claim we're arguing
7 about here, that is what the jury is going to decide, at the
8 cash register what were the facts.

9 The facts were it had two out of the five things it
10 was supposed to have. And the jury can put that together and
11 decide, well, where is the value for it. Our expert says this
12 is the full value and if you give a full refund, it would be
13 this. If you didn't give a full refund, you figure out where
14 it falls. And the jury makes that call, like they do in cases
15 all the time where they decide how much does a person get for
16 getting run over by a truck, for getting broken bones. And
17 there's no guidance in New Jersey on how to value that, and
18 juries do it every single day. There's nothing that's so
19 esoteric about this that a jury can't decide it.

20 So, again -- I'm sorry, Your Honor.

21 CHIEF JUDGE BUMB: How do you get to zero value?

22 MR. SLATER: Well, I was actually arguing in the
23 sense that, I could repeat it again, that if Your Honor says I
24 am not going to let you -- I thought you were going to --
25 you've decided there's no way I'm letting you argue zero value,

1 so --

2 CHIEF JUDGE BUMB: How do you get to zero value?

3 MR. SLATER: How do we get there?

4 CHIEF JUDGE BUMB: Yeah.

5 MR. SLATER: We say at the cash register, you're not
6 allowed as a matter of law, this is the evidence, this is the
7 law, to sell because it's got three -- it's got two out of the
8 five attributes. You can't do it. If it doesn't have all five
9 attributes, it's illegal to sell it because it's not the
10 approved form the FDA lets you sell. And, therefore, and we
11 obviously talk about why that happens and that their witnesses
12 admit that they could not sell it. They were not supposed to
13 sell it.

14 And then they argue, well, you know, there was
15 efficacy so even though it slipped through, they got some
16 value. But that's for the jury to decide at worst.

17 CHIEF JUDGE BUMB: But then you have to come forward
18 and say it had zero value, not simply because it had a
19 contaminant, but because it had zero value, it didn't do what
20 it said it was supposed to do, addressing those five factors
21 that you want to talk about.

22 You can argue that it had a fundamental defect, it
23 didn't lower blood pressure, maybe it did, maybe it didn't.
24 But the fact that it caused cancer was, you know, overrode
25 everything and, therefore, it has zero value. That's how the

1 "benefit of the bargain" goes. We've got to make sure that
2 we're talking about liability versus damages.

3 But this is how -- I keep going back to it, the
4 plaintiffs want to stand up and say, ladies and gentlemen of
5 the jury, here's my case, here's our case. It turns out that
6 when we paid for these drugs at the counter they had
7 contaminants in them. They weren't supposed to have
8 contaminants in them. It was illegal to have contaminants in
9 them, give us a full refund, sit down. The trial will take
10 five minutes, sit down.

11 MR. SLATER: And --

12 CHIEF JUDGE BUMB: That's not --

13 MR. SLATER: But that's not --

14 CHIEF JUDGE BUMB: That's --

15 MR. SLATER: We're not going to be that simple
16 though, Judge. And we're not --

17 CHIEF JUDGE BUMB: But that's your case. No. But
18 that's your case in a nutshell. And --

19 MR. SLATER: But it's not, it's not, because you left
20 out a very important part of our argument. And your
21 hypotheticals were like what if it was some kind of
22 nonmaterial -- there could be cGMP violations, the label was
23 smudged. There's a million examples you can come up with.

24 CHIEF JUDGE BUMB: Right.

25 MR. SLATER: But we're not walking in and saying, you

1 know, the law actually says that if there were rampant cGMP
2 violations in the facility, every pill, every drug that goes
3 out of there is technically contaminated, is technically
4 adulterated. We're not arguing that. We're not going for some
5 de minimis technical win. We're not just saying because it was
6 contaminated.

7 We're saying because it was contaminated with
8 genotoxic impurities that are in the cohort of concern, that
9 were barred from being in these drugs, and it was not
10 manufactured, A, in conformance with cGMPs, which is one
11 independent basis to establish adulteration, and, two, did not
12 meet the compendial specifications that they represented it did
13 which is a second basis for adulteration, both of which we are
14 arguing and both of which we have evidence for, and our expert
15 will address and explain, because it was such a significant --
16 because the contamination was so significant in terms of what
17 it's rated as and what its potential impact was, its risk,
18 because of that significance, and that's where we think the
19 materiality prong goes in.

20 And Judge Kugler had the same concern. You got to
21 show that it matters. But in a regulatory case, as Dr. Chodosh
22 testified under oath, it's the risk level from a regulatory
23 standpoint, which is protective and conservative towards
24 safety, and that's why we're saying it didn't have value,
25 because what they said was not true and you could not legally

1 sell it.

2 Those pills were not legally sold. They were sold
3 and it slipped through, but that doesn't give them the excuse
4 to say, well, no harm, no foul, we did it, and it helped.

5 They're going to argue, well, you know what, it turns
6 out, ladies and gentlemen, yeah, we probably shouldn't have
7 sold it, we figured it out eventually, but it did help them, so
8 they should get some value. Their expert is going to be
9 allowed to say that. Your Honor's letting Dr. Stiroh say it.
10 She has no methodology to value the efficacy. So we're in the
11 position, I think, of looking at what are the attributes of the
12 pill. What are the things that you have to have in order to
13 get approved to meet the USP criteria, and the jury decides it.

14 General causation does not belong because that's not
15 a factor at all.

16 CHIEF JUDGE BUMB: I don't know. I sit here, because
17 when I was first assigned the case, I recall reading the
18 parties' submissions. And one of the concerns that I had, as I
19 read what the defendants had written, that proceeding in this
20 fashion was novel. The way that Judge Kugler had decided to
21 proceed was novel; that this Court would create reversible
22 error if it did proceed in this way. I considered it all. I
23 saw the wisdom in it at the time. But what has happened since
24 then is despite my efforts to drill down, drill down and talk
25 about evidence, I keep getting argument.

1 Now, what you've just said to me, Mr. Slater, says to
2 me -- you say things like the jury's going to hear that it had
3 a genotoxic contaminant; that it was unsafe; that the plaintiff
4 has to show that that matters, that all says to me what the
5 defendants have been quarreling about, which is how can they
6 try this case without causation.

7 And I get right back to it and I don't know. I don't
8 know how the plaintiff can stand up before -- and I know you
9 folks have been arguing about, you know, the depositions and
10 these really ugly words that are being used, and I don't know
11 how the plaintiffs can get up and say all of these really --
12 genotoxic and mutants and really, really scary words without
13 addressing the elephant in the room. And that is, well, are we
14 talking about, you know, a little speck of flour in these
15 things or are we talking about cancer that kills?

16 And I don't know how the plaintiffs walk that fine
17 line. I've remained concerned about it under 403 for a long
18 time. I just don't see how the case can be tried without
19 causation, I don't; I just simply don't.

20 MR. SLATER: The --

21 CHIEF JUDGE BUMB: You have tried to persuade me. I
22 keep coming back and saying why would I try a five-week trial,
23 a four-week trial knowing that it's coming back. And I'm not
24 going to try a four- or five-week trial if I don't have the
25 comfort that I am -- that this is -- that I'm comporting -- I

1 think I'm comporting with the rules of evidence and I'm
2 comporting with the law. I just -- I think it's -- there's two
3 problems, maybe three.

4 It's argument versus evidence. It's liability versus
5 damages. There's a lot of conflating going forward.
6 There's -- now the other issue is, are we talking about it has
7 zero value because it's like a sugar pill or are we talking
8 about it's a fundamental defect because it is a genotoxic
9 contaminant? And if that's the case and it causes cancer, then
10 we should get a full refund. Or are we talking about it's a
11 sugar pill and we should get a full refund because it's
12 completely inefficacious? Or is the jury going to weigh both
13 of those and say, well, there was a therapeutic value, the
14 chance of getting cancer was so nil and the FDA said sell it
15 anyway even after the recall. So that is where I think the
16 robust discussion in the jury box is going to happen, which is
17 what is the value.

18 Plaintiffs keep wanting to come back and saying it
19 should never have been sold, period, it was illegal to sell it,
20 we get our full refund. And then we get into another argument
21 that I haven't even gotten to, which is the defendants'
22 argument, which is, well, if they're going to make that
23 argument, they don't just get a free ride here, particularly in
24 the absence of fraud, because we didn't know it contained
25 nitrosamine.

1 And that appeals to me, because I think if the jury
2 finds that they didn't know, I mean, does that mean that the
3 plaintiffs get a full windfall?

4 These are all questions that, you know, what, three
5 weeks before trial continue to swirl around, and I still don't
6 have clarity on. I'm not going to try a case unless I have
7 clarity on it. And sitting here today, as you can tell, I don't
8 have clarity; I just don't.

9 And part of the problem is I think the motion to
10 dismiss was somewhat far broader than the motion for summary
11 judgment. I think there were -- I think perhaps there -- you
12 know, I can reconcile those two documents because of the
13 pleadings stage. One was a pleadings stage and one was summary
14 judgment stage. But -- I don't know.

15 MR. SLATER: You know, Judge, it's interesting
16 because you haven't heard from the defense where they've
17 actually pointed to the law or what actually happened here in
18 terms of the warranty claim, in terms of the fact that these
19 shouldn't have been sold, where they haven't -- they've never
20 pointed to you and said, well, you know, the FDA or the law in
21 general says that if it actually caused cancer, that's a
22 touchstone to whether the drugs could or could not be sold
23 because that's not the law. The law --

24 CHIEF JUDGE BUMB: Well, they -- I don't -- what --
25 they are not disputing that once the contaminant -- we have to

1 deal in what the facts are.

2 MR. SLATER: That's what --

3 CHIEF JUDGE BUMB: Their evidence, presumably,
4 they're going to -- well, if they're going to put in evidence
5 that, you know, yeah, we knew from day one it contained this
6 and we sold it anyway, well, then that's their issue, and I'm
7 sure you're happy about it.

8 But they're not -- the evidence is going to be, I
9 presume, that at the time that they found that it contained the
10 contaminant, they advised the FDA and the FDA issued the
11 recall. That's why I'm saying we have to deal in what the
12 facts are.

13 Plaintiff is going to come forward and say, well, no,
14 it was adulterated from day one because this is what the
15 evidence shows; that given the process that they used, it
16 produced this contaminant from day one, and we should get -- we
17 should get our money back, not because it was illegal to sell,
18 but because it was not the "benefit of the bargain." It was
19 more harm than it was efficacious, number one.

20 And number two, you know, dealing with the fraud,
21 well, we get a full refund plus some because they knew and they
22 hid it from the FDA. But we're not even dealing with the
23 fraud. We keep focusing on the express warranty.

24 MR. SLATER: Well, the --

25 CHIEF JUDGE BUMB: I feel like I keep talking in

1 circles up here; I really do.

2 MR. SLATER: Well, when you talk about why we are
3 entitled to recover, you asked why are you entitled, why are
4 you entitled to recover, it's a breach of warranty claim. The
5 reasons that they breached the warranty matter.

6 CHIEF JUDGE BUMB: Exactly. You keep saying that.
7 And that's why causation matters.

8 MR. SLATER: But there is no causation prong in a
9 warranty claim.

10 CHIEF JUDGE BUMB: That --

11 MR. SLATER: It's not an element of the claim, Your
12 Honor.

13 CHIEF JUDGE BUMB: It's an element of damages.
14 Focus, liability. Focus on liability and then focus on
15 damages. Focus on the elements of showing a breach of
16 warranty. That goes to liability. Now we've got to deal with
17 damages.

18 Is it an element of liability? No.

19 MR. SLATER: Of course.

20 CHIEF JUDGE BUMB: Is it an element of damages? Yes.

21 MR. SLATER: The only causation, quote-unquote
22 causation for a warranty claim is did it -- if it didn't comply
23 with the warranty, you're entitled to get your money back.

24 To the extent that Your Honor -- and I know I've said
25 this before and I know I've just said it a few minutes ago --

1 to the extent the Court has a concern that you don't want some
2 de minimis technical violation to be the basis for our
3 argument, we are not arguing that.

4 CHIEF JUDGE BUMB: No; I know. I think you're
5 arguing -- I think you're arguing what is called a fundamental
6 defect in the product.

7 MR. SLATER: It clearly is a fundamental defect.

8 CHIEF JUDGE BUMB: Okay. And so that to me says what
9 makes it a fundamental defect, because it doesn't do what it's
10 supposed to do, it actually is more harmful than what it's
11 supposed to do. To me that sounds like causation.

12 MR. SLATER: Well --

13 CHIEF JUDGE BUMB: "Materiality," "fundamental,"
14 those are all words that to me say causation. They all say to
15 me -- I now see the wisdom of what the defendants are saying to
16 me why maybe perhaps personal injury cases are tried first,
17 because they make more sense.

18 MR. SLATER: Can I ask a question, Judge?

19 One option you have is to say to us, I'm letting
20 causation in. I'm going to let the defendants argue that
21 there's no evidence that this could have ever caused cancer in
22 the amounts that was in there.

23 CHIEF JUDGE BUMB: Uh-huh.

24 MR. SLATER: We wouldn't be happy about it. We'd
25 have to add a bunch of testimony back into our designations,

1 because we have devastating admissions from the witnesses; for
2 example, admitting that the treatise they cited in their
3 submissions to the FDA from the World Health Organization says
4 it's likely to cause cancer in humans, for example. We took
5 that out of our designations. We have a lot of evidence on
6 that. We bring in our -- one of our experts or two of our
7 experts to -- and honestly, Your Honor, I don't think you've
8 already -- if you were to let it in, I assume it wouldn't be a
9 full-blown causation trial. They'd have Dr. Chodosh. We'd
10 bring an expert in.

11 I'm previewing it for the defense. I don't know how
12 they get around the only studies that have ever been done on
13 the pills that show it actually does have a significant -- an
14 increased risk of cancer that's statistically significant.

15 So I guess Your Honor could say, look, if we're going
16 to trial, I'm going to let them argue causation. We put
17 guardrails around it. We put our evidence back in. We won't
18 be happy about it. The case is going to take longer because
19 there's going to be more witnesses and more testimony, but
20 we'll have to deal with that. And there's no way that we --
21 and there's nothing that we can do about that. And --

22 CHIEF JUDGE BUMB: And that is your worth less, two
23 words, case.

24 MR. SLATER: Well, I think it's our no worth or our
25 worth less case because in that case we're going to be

1 allowed --

2 CHIEF JUDGE BUMB: It could be.

3 MR. SLATER: Because remember, they blocked us from
4 proving it causes cancer. That was their in-limine motion to
5 block us. So now that in-limine motion, you'd have to change
6 your ruling, because obviously you'd have to vacate it because
7 they've changed their position, and then we would put in
8 evidence that it does cause cancer, and then all this would
9 come in. And now, you know what, maybe it's better for us on
10 appeal if they do that.

11 CHIEF JUDGE BUMB: No. I think --

12 MR. SLATER: Because --

13 CHIEF JUDGE BUMB: To be fair, I think that the
14 confusion came from a ruling from Judge Kugler that causation
15 was not to be a part of this trial. And so that's my
16 recollection, though someone will correct me if I'm wrong. And
17 as a result, there was a motion that since it wasn't going to
18 be part of this trial, that it needed to be kept out by the
19 plaintiffs. And based upon that, with those parameters, I
20 ruled that. But as I've said, I've gone back and forth and
21 back and forth. And I don't know how it doesn't become part of
22 this trial.

23 MR. SLATER: I don't --

24 CHIEF JUDGE BUMB: Does anyone agree with me on this
25 side?

1 MR. SLATER: I don't think that's correct, Your
2 Honor, because they also in the motions, the same motions, they
3 argue general causation is a part of the case. Remember --

4 CHIEF JUDGE BUMB: A part of the case.

5 MR. SLATER: Yeah. They wanted general -- we briefed
6 the in-limine motions. One of their motions was we should not
7 be allowed to tell the jury that this caused cancer in people,
8 we shouldn't be able to argue it, suggest it, or anything else.
9 They also argued general causation should come in, and we
10 argued it shouldn't. And that was an issue that Your Honor
11 addressed on July 23rd.

12 So I think that, really, what I'm saying to you is if
13 that's the only way we're going to try the warranty claim,
14 because, again, I don't think it's an issue with the other two
15 claims. The other two claims are it was deceptive conduct and
16 outright fraud. Those two claims are different because that's
17 where we're actually saying you actively deceived. The
18 warranty claim is the warranty -- there's an element of
19 deception in that, but the warranty claim is you said it was
20 this; it wasn't. And you said it has to matter, though. I'm
21 paraphrasing. And we agree with that. It has to matter. And
22 that's materiality under the regulatory law that applies here.

23 Dr. Chodosh said exactly the same thing Judge Kugler
24 said. He said it's two different standards. We're not
25 applying biological causation in this case because that's not

1 what the law is. That's not the reason they pulled this off
2 the market. No one ever studied this to say in these amounts,
3 in these pills it causes cancer so that's why there's a recall.
4 No. It's because they're genotoxic probable human carcinogens
5 that have been looked at for many, many years. There's
6 regulations going back to the early 2000s and before, but
7 certainly by 2008 the FDA said you can't have these in the
8 drugs. These are very dangerous substances. It can't be in
9 there. And if you want to have it in there, you have to
10 analyze it up front, you have to come to us and we'll make a
11 decision. And they never did that so it wasn't allowed.

12 So the causation is not part of this case as a matter
13 of law and as a matter of fact because it was never looked at.
14 When you look at why these drugs were pulled off the market,
15 Judge, that's just what it is, though. The reason the drugs
16 were pulled off the market is because it had NDMA in it, not
17 because the FDA found it's going to cause cancer.

18 CHIEF JUDGE BUMB: No; I know that.

19 MR. SLATER: And, by the way, they eventually did do
20 an analysis and said we think 1 in 8,000 people would have an
21 increased risk of cancer, and they did these analyses and they
22 did their whatever. But they said, yes, more people are going
23 to -- because people are going to get cancer.

24 But, you know, if the answer is, I'm not letting you
25 try the warranty claim without the causation, then we have to

1 live with that. And maybe that's good for us, because then we
2 don't have to worry about it being tried without it. They have
3 nothing to argue about on appeal. And then maybe it helps the
4 Court to feel more comfortable.

5 CHIEF JUDGE BUMB: All right. Let me just hear from
6 them.

7 And the other thing, I just want to say it while it's
8 on top-of-mind, which is I think it's incorrect to say to the
9 jury that it's illegal -- it was illegal for the defendants to
10 sell these drugs in 2012, because illegal says that they
11 violated the law.

12 It is true that as a matter of law adulterated drugs
13 can't be sold, that is true.

14 MR. SLATER: So we say it that way.

15 CHIEF JUDGE BUMB: Well, yeah, but words matter.

16 MR. SLATER: They matter. But here's the problem: I
17 think one of the big things the Court might be wrestling with
18 in the abstract --

19 CHIEF JUDGE BUMB: What I'm wrestling with is that
20 the plaintiffs just keep making arguments and not backing it up
21 with evidence. And I'm very frustrated by it. Can you see?

22 MR. SLATER: The evidence is that the condition of
23 these pills, based on how they were manufactured and what ended
24 up in them, violated the specifications, violated cGMPs,
25 rendered them contaminated, et cetera. And as a matter of law,

1 because we argue that they met the statutory definition -- this
2 is not argument, this is evidence. Our experts are going to
3 say it met the statutory definition of adulteration.

4 CHIEF JUDGE BUMB: They are not -- they are not
5 permitted to be sold. But unless and until you prove that they
6 knew what they were selling was contaminated, it is not proper
7 argument to say that they illegally sold them.

8 MR. SLATER: But it's not an element of the claim,
9 Judge. I mean, I get that you --

10 CHIEF JUDGE BUMB: But it's a 403 issue.

11 MR. SLATER: We're going to now create more hurdles
12 for us to get over --

13 CHIEF JUDGE BUMB: No. You've got to --

14 MR. SLATER: -- on a claim where knowledge is not an
15 element of an express warranty claim. It's an element of --

16 CHIEF JUDGE BUMB: I'm talking --

17 MR. SLATER: -- the fraud claim, but it is not an
18 element of this claim. I'm sorry, Judge. I don't mean to
19 interrupt you.

20 CHIEF JUDGE BUMB: I'm talking about how -- the
21 arguments that you're presenting to the jury. You've got to be
22 very careful.

23 I mean, you've just got to be very careful and
24 precise on what your arguments are.

25 Let me hear from Ms. Lockard.

1 MS. LOCKARD: Thank you. Thank you, Judge. I've
2 been listening very patiently for my opportunity.

3 Just to clarify a couple of points that Your Honor
4 has picked up on. We absolutely disagree with the contention
5 that we think we did anything illegal in selling these drugs.

6 The FDA itself, if you want to talk about evidence,
7 we have a statement from the FDA that explains it, which
8 basically says from Commissioner Gottlieb at the FDA that it
9 needs to be recognized that there is a risk of an impurity
10 occurring to know that it should be tested for. Before we
11 undertook this analysis, meaning FDA, neither regulators nor
12 industry fully understood how the nitrosamines could form
13 during the manufacturing process. That's evidence. That's
14 from the FDA. That will come in.

15 So --

16 CHIEF JUDGE BUMB: Right. And then they'll respond
17 with the warning letter and then your expert's admission. I
18 mean, I understand that's the back and forth.

19 MS. LOCKARD: Correct.

20 CHIEF JUDGE BUMB: And that's a jury question.

21 MS. LOCKARD: So then we'll fight about whether there
22 was a cGMP violation, whether the products were adulterated.
23 Both sides have their position on that.

24 The issue, though, is on the general causation -- and
25 by the way, the motion in limine that Mr. Slater is referring

1 to, it's Motion in Limine No. 10 by the defendants. And it was
2 to exclude evidence or reference to individuals, individuals,
3 who used valsartan and developed cancer. So we didn't want
4 them to come in and say, oh, we've got all these other clients
5 who are suing has cancer. That's what that motion was about.
6 It wasn't about general causation.

7 So, you know, obviously our position is set forth in
8 the papers. And as you recognize, Judge, you said it is the
9 elephant in the room. And we agree we don't need to get into a
10 full epidemiology trial and spend days talking about this. And
11 the literature that Mr. Slater has referred to, we absolutely
12 have responses to that, as to why it's not reliable, why it
13 doesn't matter, why it doesn't prove that these drugs cause
14 cancer. Dr. Chodosh can speak to that as well as other experts
15 we have. We have epidemiology and toxicologists if we blow it
16 up that much.

17 But the important thing is plaintiff wants to be able
18 to come in and say, well, it was an unacceptable risk. That's
19 what the FDA said. And that's the regulatory risk.

20 And Your Honor asked about the difference between
21 biological risk and regulatory risk. The issue is that the
22 FDA's obligation is to make sure there are safe drugs on the
23 market. The way they do that is they want to ensure that the
24 drugs that are being marketed are free from unreasonable risk.

25 So the FDA never undertook to determine if these

1 drugs caused cancer. They never did. At the time when all of
2 this came to light, the FDA was acting very fast and furiously
3 to get this resolved because there are, you know, millions of
4 patients taking these drugs. And FDA, as you know,
5 Commissioner Gottlieb said this is a new issue. They sprang
6 into action and they said we've got to do something. We've got
7 to get some guidance, so we're going to come up with some sort
8 of limits and standards that can be easily and quickly applied.
9 And so what they did -- and in our submission with, as we've
10 described, Dr. Chodosh's testimony, the FDA came up with these
11 limitations based on a linear low dose extrapolation from
12 animal studies.

13 Now, that presumes that extremely low doses of the
14 substance are potentially carcinogenic over the course of the
15 lifetime, based on an assumption that they drew from studies
16 where these massive amounts were given. And so all they did is
17 they did a straight-line extrapolation and said, well, we know
18 if this amount causes cancer in rats, you know, let's
19 straight-line extrapolate it down to a limit that we can be
20 assured is safe.

21 They didn't say anything below that level is unsafe
22 or causes cancer. They just said, look, let's stop it here.
23 We know if we stop it here and we apply these limits that
24 everything on the market will be free of unreasonable risk.

25 That raises the question, though, it's unanswered

1 through that, it's unanswered through the FDA levels as to
2 whether what was actually on the market causes cancer.

3 CHIEF JUDGE BUMB: Well, the concern I have is that
4 once the jury hears that it's free from an unreasonable risk,
5 it raises the question risk from what?

6 MS. LOCKARD: Exactly.

7 CHIEF JUDGE BUMB: And now we're back to causation;
8 that there is this potential that it could cause cancer, et
9 cetera.

10 And I think to somehow water it down and argue to the
11 jury that, well, the FDA determined that this poses an
12 unacceptable risk when they recalled it and, therefore, on day
13 one it posed an unacceptable risk, it still leaves open the
14 question of risk from what?

15 MS. LOCKARD: And it has to be said, in the
16 unacceptable -- our position and our -- this is our argument to
17 the jury would be that it's an unacceptable risk to have the
18 drug on the market. That's all the FDA was saying. It's an
19 unacceptable risk, because we don't know at present what level
20 would actually cause cancer, if any. But we know that if we
21 keep it at this level and we let anything that's below this
22 level on the market, we know it's safe. But safe from what?
23 What is the risk?

24 So you have to be able to explain, well, we're
25 talking about carcinogenicity. So the next question to the

1 jury is, well, what is the real risk? You know, does anyone
2 get cancer? What do we -- nobody has presented that. And if
3 defense is not able to present the biological risk and the real
4 evidence from the scientists and the biologists and the cancer
5 researchers, the jury is left with concluding that oh, well,
6 defense must concede this; that the drugs that were on the
7 market did cause cancer. And that, we feel, that is the root
8 of the error in proceeding in this way.

9 CHIEF JUDGE BUMB: And so the breach of warranty is
10 the difference at the time and place of acceptance between the
11 value of the goods accepted and the value they would have had
12 if they had been as warranted.

13 And so to say to the jury that they had no value
14 because they posed an unacceptable risk deprives the jury of
15 knowing what that risk is and deprives the jury of any evidence
16 in determining what that value might be, because -- I -- I --
17 yeah.

18 MR. SLATER: Your Honor.

19 CHIEF JUDGE BUMB: Yeah.

20 MR. SLATER: We don't want to deprive the jury of
21 evidence.

22 CHIEF JUDGE BUMB: What?

23 MR. SLATER: We don't want to -- I'm sorry. We don't
24 want to deprive the jury of evidence.

25 We want to say exactly what defense counsel just

1 conceded. It was an unacceptable risk to have the drug on the
2 market. What was the unacceptable risk? It was unacceptable
3 carcinogenic risk from a regulatory standpoint. And we've
4 submitted to Your Honor a limiting instruction that explains to
5 the jury exactly what that means, exactly what they will decide
6 and what they won't decide.

7 They agree that having that NDMA in those pills was
8 unacceptable and you can't sell it. That's the law that
9 applies to this claim.

10 Now -- so we're not saying don't tell the jury what
11 the risk is. We're going to put in the guidelines from ICH and
12 the FDA. And their own -- ZHP had an internal standard
13 operating procedure that went back to 2011 that said they had
14 to identify every genotoxic carcinogen or genotoxic impurity
15 because they knew that this was unacceptable. This is a
16 regulatory safety issue, as counsel just argued. That's what
17 Dr. Chodosh said.

18 I think a big part of the problem is, the facts and
19 the law are very one-sided in this case. I mean, I think
20 that -- and I'm trying to be a psychologist here a little bit,
21 because I think Judge Kugler had the same concern you have,
22 which is this is so one-sided, how do they have a defense? And
23 he said I'm going to let the jury decide some of these
24 questions.

25 The law and the facts -- because the facts are so

1 one-sided and so disturbing and because the law is so clear, it
2 is a very, very one-sided case. And they're saying, well, let
3 us argue things that don't apply in this context. Let us apply
4 general causation. And you know what, Judge, we're saying,
5 over our objection, if you say it has to come in, then let's
6 try the case with general causation in it. We'll do it. We're
7 not going to run away from it. We'll have to do it. And it
8 may be great for us on appeal that if we had to try it, they
9 have nothing to complain about. But we don't want to hide from
10 the jury what's being tried. We don't want to hide what the
11 risk is. They need to know that. That's why it mattered at
12 the cash register because it wasn't a smudged label. It wasn't
13 a piece of flour. It was something that was real and
14 dangerous, and as they say, as counsel just argued, the FDA
15 looked at this and said we're not analyzing whether it causes
16 cancer in these amounts. This is something that we've known
17 for many, many years. We can't have these impurities. They're
18 a cohort of concern. They're very toxic.

19 I mean, we know what NDMA is used for. It's
20 deliberately used to give cancer to lab animals. That's how
21 it's used in the laboratory. It's a very dangerous substance.

22 If they really want to join this and counsel really
23 wants to stand up and say, you know what, ladies and gentlemen,
24 yeah, we shouldn't have sold it and we weren't supposed to sell
25 it, I don't know, I guess you'd have to fashion some

1 instruction to tell them why you're letting them argue general
2 causation. Maybe you say, well, this goes to damages but not
3 liability, because the liability didn't factor in general
4 causation, but however the Court would do it. And they argue
5 you know what, yeah, we sold this stuff and, yeah, we didn't
6 know it was there, but you know what, it turns out we've got
7 Dr. Chodosh who's going to tell you it doesn't cause cancer in
8 those amounts.

9 You know what, maybe the jury after they hear our
10 evidence there says, you know what, how dare these people, how
11 dare they come in here after they've put this into our drug
12 supply and say, well, you know what, it's no harm, no foul
13 because it was too little to cause you cancer.

14 You know what, maybe with punitive claims, maybe
15 that's the best thing they could ever argue for us. And we'll
16 live with it, Judge. I mean, at this point we just want to try
17 this case. I'm not agreeing that it would be the right
18 outcome, but reasonable minds can differ. And your mind is
19 much more important than my mind. So if that's what you rule,
20 then we'll try the case like that. We'll have no choice and
21 we'll do it.

22 CHIEF JUDGE BUMB: Let me take a break. I'll be
23 back.

24 THE COURTROOM DEPUTY: All rise.

25 (Recess was taken at 2:22 p.m. until 2:48 p.m.)

1 THE COURTROOM DEPUTY: All rise.

2 CHIEF JUDGE BUMB: Okay. You can have a seat.

3 Where did we leave off? Somebody wanted to say
4 something to me.

5 MR. OSTFELD: Your Honor, there was just one point
6 that I wanted to raise that I neglected to raise during the
7 initial conversation about the diminished value, the worth
8 less, two words, theory, which is that Judge Kugler actually
9 dismissed that theory on standing grounds in his Motion to
10 Dismiss Opinion No. 2. It's document 728 at pages 11 and again
11 at page 13.

12 What he essentially says --

13 CHIEF JUDGE BUMB: Wait. Let me get to it. Hang on.

14 MR. OSTFELD: I'm sorry, Your Honor.

15 CHIEF JUDGE BUMB: What page?

16 MR. OSTFELD: So it's at page 11 is kind of the
17 introduction to that, at the bottom of the first full
18 paragraph, and then the substantive discussion of it is on
19 page 13.

20 Where Judge Kugler writes, the second theory of
21 economic loss, the receipt of a less valuable product would
22 have sufficed --

23 CHIEF JUDGE BUMB: Wait. I'm sorry. I don't see it.

24 MR. OSTFELD: Oh, I'm so sorry, Your Honor.

25 CHIEF JUDGE BUMB: That's all right. Motion to

1 dismiss opinion.

2 MR. OSTFELD: Opinion No. 2, document 728.

3 CHIEF JUDGE BUMB: Oh. Okay. I'm on the wrong
4 opinion. Hang on.

5 Well, maybe I don't have it. I have the 775 opinion.

6 MR. OSTFELD: Okay.

7 CHIEF JUDGE BUMB: Let me hear it.

8 MR. OSTFELD: Okay. So I'll read both sections,
9 then, Your Honor.

10 CHIEF JUDGE BUMB: Okay.

11 MR. OSTFELD: Beginning on page 11 of document 728,
12 Judge Kugler first identified plaintiffs' three theories of
13 economic injury. He identified them. The first theory was
14 receipt of a worthless, one word, product because of the
15 failure to receive the "benefit of the bargain." The second
16 was receipt of a less valuable product because of the failure
17 to receive the "benefit of the bargain." The third was
18 economic loss from having to purchase replacement medication
19 due to the voluntary recalls.

20 CHIEF JUDGE BUMB: Okay.

21 MR. OSTFELD: What he found at the --

22 CHIEF JUDGE BUMB: Wait. Hang on one second. Let me
23 just...

24 MR. OSTFELD: I'm sorry.

25 CHIEF JUDGE BUMB: Let me just read it.

1 Okay.

2 MR. OSTFELD: All right. And he found the first and
3 third theories satisfied standing. He found the second theory,
4 the worth less, two word, theory, "fails to allege facts which
5 would permit a fact finder to value the purported injury
6 with" -- I think he meant without, but it says "with resorting
7 to mere conjecture."

8 The analysis for that then comes on page 13. On the
9 second full paragraph, Judge Kugler writes: "The second theory
10 of economic loss, the receipt of a less valuable product would
11 have sufficed to establish an injury in fact if plaintiffs had
12 provided a theory for the fact finder to value it, but they do
13 not. Instead, they would have the fact finder resort to mere
14 conjecture to value their purported injury. This second theory
15 is insufficient to confer standing."

16 CHIEF JUDGE BUMB: That's the *Zantac* ruling.

17 MR. OSTFELD: That is the *Zantac* Opinion. And it
18 applies equally here. And it also applies -- of course,
19 standing is reevaluated at each stage. And here we are at the
20 trial stage, and it applies with equal force here.

21 Plaintiffs still do not have any evidence, economic
22 survey, otherwise, that would allow the fact finder without
23 resorting to mere conjecture to value the purported injury for
24 diminution of value.

25 So we can certainly have a trial where general

1 causation comes in, but it's binary. It's worthless, that's
2 the theory they've gone all in on. If they can't prove that
3 it's worthless, it doesn't go to the jury.

4 CHIEF JUDGE BUMB: You have to -- you have to say
5 that again because the record's not going to reflect what
6 you -- you have to say one word and two words.

7 MR. OSTFELD: Okay. I'm sorry, Your Honor.

8 It's their theory, the plaintiffs have strategically
9 gone all in on, one word, worthless as their theory of damages.
10 That is the only evidence they were prepared to present to the
11 jury through Professor Conti, and that opinion has been
12 excluded.

13 So where we are now, they do not have economic
14 damages evidence for their worthless, one word, theory. They
15 have never had and do not have economic damages for their worth
16 less, two words, theory, which was dismissed for lack of
17 standing at the motion-to-dismiss stage.

18 So I think we're back to Your Honor's suggestion,
19 which is this is now a summary judgment matter. There is no
20 evidence to present on damages at trial. There is no evidence
21 to take this to a jury. Therefore, I can make an oral motion,
22 we can make a written motion, but we believe this case is now a
23 summary judgment case.

24 CHIEF JUDGE BUMB: You want to respond.

25 MR. SLATER: I didn't understand that Your Honor

1 actually ruled that we cannot put in the no-value theory,
2 number one.

3 Number two, I'd have to look again at these rulings.
4 I obviously have not looked at them in a long time. But we
5 certainly believe, before even getting to that issue, and,
6 again, I would want to look at the decision -- and as counsel
7 just said, standing gets reevaluated at various stages of the
8 case. I've made arguments here as to how it would be valued,
9 arguments that were never presented at that time because it was
10 a much more flat record. We hadn't done the -- we hadn't
11 developed the case. So if the standing issue is now going to
12 be challenged on worth less, then we would obviously be able to
13 present arguments such as we made here today.

14 CHIEF JUDGE BUMB: Well, no. I think the issue that
15 Judge Kugler had from what's being presented is that the
16 plaintiff alleged no facts to support a value worth less, two
17 words, and so that claim was out.

18 And it reminds me of what Judge Rosenberg ruled: "In
19 this MDL, the plaintiffs attempted, but were unable, to put
20 forward reliable evidence to prove that ranitidine was unsafe,
21 which now changes the Court's standing analysis."

22 It says, "During the motion-to-dismiss stage, the
23 standing theory on which the plaintiffs relied for their
24 economic loss claim had some similarities to *Debernardis* and
25 *Aqua Dots* because the Court found that the plaintiffs plausibly

1 alleged that the drug was unsafe and should not have been
2 sold."

3 It's a little different, because then the Court --
4 because she did preclude the testimony under *Daubert*. The
5 plaintiffs could no longer claim that the drug was unsafe or
6 should not have been sold because of its cancer-causing
7 propensity.

8 And I'm understanding from Judge Kugler's Opinion
9 that the complaint here -- the operative complaint here never
10 alleged that the drugs should never have been sold because of
11 its cancer-causing propensity. I don't know.

12 MR. SLATER: I mean, that's been a fundamental
13 allegation in the case all along that --

14 CHIEF JUDGE BUMB: I don't know. From what was read
15 to me, of course I didn't have the Opinion in front of me.

16 MR. SLATER: In our case. I don't know --

17 CHIEF JUDGE BUMB: The Judge seemed to find that you
18 were not making that allegation and, therefore, the claim was
19 out.

20 And, you know, as Mr. Ostfeld says, you made the
21 strategic choice to go, you know, all in with the worthless,
22 one word, theory. It shouldn't have been sold, therefore,
23 they're worthless.

24 MR. SLATER: Well, I think if we're going to talk
25 about what Judge Kugler did, he said that it's a jury question

1 about whether there was any value or not.

2 And I want to add something to what we talked about
3 before, because you're asking what is the evidence.

4 CHIEF JUDGE BUMB: That's true. I mean, it does
5 sound as if they're -- how can I put this? It does sound as if
6 there's -- I'd have to look to see how I can reconcile the
7 motion to dismiss with the summary judgment opinion.

8 Yes?

9 MR. SLATER: I think one of the other things that's
10 important in terms of you're asking us what is our evidence
11 about the value not being -- having no value, the evidence of
12 no value.

13 One of the other things that's important to remember
14 here is, unlike in *Zantac* where all Zantac was contaminated, in
15 this case all valsartan and all sartans and all blood pressure
16 pills were not contaminated, number one.

17 So if we look at the warranty claim, a person walks
18 up to the cash register and now they're presented with, in
19 their version of the case, which Your Honor's allowing them to
20 argue, well, there was efficacy so there's value. So
21 essentially the argument is, well, if a consumer had a choice
22 they still would have paid less but they wouldn't have had to
23 pay nothing, okay.

24 CHIEF JUDGE BUMB: Uh-huh. Yes.

25 MR. SLATER: But that could never have happened. Our

1 evidence is, because we have the evidence, the TPP
2 representatives are going to testify that the way the formulary
3 works is the TPP cannot buy a drug that does not comply with
4 the compendium.

5 CHIEF JUDGE BUMB: Right.

6 MR. SLATER: So --

7 CHIEF JUDGE BUMB: But they did.

8 MR. SLATER: But if they were told this is a drug
9 that has efficacy but doesn't have safety, quality, and purity,
10 it could not have been sold. So in terms of what the evidence
11 is about the value at the time of the register from the TPPs'
12 standpoint, they would not have paid anything for the pills
13 that were not in compliance because they can't. They're not
14 allowed to. They --

15 CHIEF JUDGE BUMB: I know. But --

16 MR. SLATER: And number two, the retailers have
17 confirmed they would not have sold it.

18 CHIEF JUDGE BUMB: I know. But those aren't the
19 facts of the case.

20 MR. SLATER: No; but it is the facts of the case.

21 CHIEF JUDGE BUMB: No, they're not.

22 MR. SLATER: Because those are the rules that
23 applied. So under the warranty law, if we're going to value at
24 the register and we're going to value what the drug is worth
25 and they're going to say, well, there's going to be efficacy,

1 it's okay that there was not going to be quality, purity,
2 safety because the efficacy gives it value, the evidence is,
3 well, what would the TPPs have paid for at that time.

4 CHIEF JUDGE BUMB: Right.

5 MR. SLATER: So if they want to introduce that, and
6 the TPPs, our evidence is going to be, wouldn't have paid for
7 it. Their argument is, well, you know what, you did pay for it
8 and you shouldn't get all your money back because it still
9 helped your customers. And the jury makes the decision. And
10 the jury makes the call on that. They decide what's the value.
11 And, again --

12 CHIEF JUDGE BUMB: I think it just -- this all
13 highlights to me why it is that it's an impermissible argument
14 to the jury, it seems to me, that a plaintiff can't just get up
15 and say we get a full refund because they should never have
16 sold it.

17 MR. SLATER: But we're not --

18 CHIEF JUDGE BUMB: Why? Because you have to, under
19 the categories that Judge Rosenberg was talking about, you have
20 to either allege that it was unsafe and, therefore, it had no
21 value, that there was such a fundamental defect and, therefore,
22 it had no value or, you know, you have to dispute that it had
23 any therapeutic value.

24 It just seems incongruous to me that the third-party
25 payors can recover under the plaintiffs' theory here, you know,

1 millions of dollars or whatever it is that they're seeking and
2 the personal injury plaintiffs may recover zero. That just
3 seems so incongruous to me that it's hard for me to -- which is
4 why I say to myself: Shouldn't causation be front and center
5 here?

6 And plaintiffs keep coming back and saying, well,
7 they should never have sold them so we get a full refund, never
8 should have sold them. But why shouldn't they have sold them?
9 Yes, they were adulterated. Yes, they were non-cGMP compliant,
10 plaintiffs will prove. But plaintiffs also have to prove that
11 they had no value. They had no value either because they were
12 sugar pills. They had no value because there was such a
13 fundamental defect, they caused cancer. But to say that they
14 had no value because they should never have sold them full stop
15 is a betrayal of the record.

16 MR. SLATER: The fundamental defect is the
17 unacceptable risk that has been conceded from a regulatory
18 standpoint.

19 CHIEF JUDGE BUMB: And that's causation. I see no --

20 MR. SLATER: But it's material --

21 CHIEF JUDGE BUMB: I see --

22 MR. SLATER: Well, whatever you want to call it, we
23 have the evidence to supply that. We have, among other things,
24 we meet the statutory definitions. We have admissions from the
25 30(b)(6) witnesses of the companies. We have the FDA saying

1 this can't be sold, that it has to be recalled and pulled off
2 the market. We have all of that evidence.

3 CHIEF JUDGE BUMB: And that's giving a value. That's
4 giving a value to the jury which is the risk was so
5 unacceptable. Call it a biological risk, whatever you want to
6 call it. Because for me I understand there's a distinction. I
7 don't think it's that salient of a one, but it does bespeak of
8 causation.

9 And, you know, and now the other issue that's being
10 raised is are you precluded, you, the plaintiffs, precluded
11 from now making this worth less, two words, argument because
12 Judge Kugler ruled that you were not making these allegations
13 before that the risks were so material, therefore, the benefits
14 did not outweigh the risk. I don't know. I'll have to go back
15 and look at that.

16 MR. SLATER: Well, if we're going to follow what
17 Judge Kugler did on the summary judgment motions, he said
18 there's enough here, you're going to a jury with this question.

19 CHIEF JUDGE BUMB: Right. And that's why I said, I
20 have to kind of somewhat reconcile the motion to dismiss with
21 the summary judgment.

22 MR. SLATER: Right.

23 CHIEF JUDGE BUMB: And perhaps somewhere along the
24 line the pleadings changed. I don't know. There were a couple
25 of different motion to dismiss orders.

1 MR. SLATER: The other thing is, and I think just to
2 relate this to -- because I know Your Honor's focused on the
3 Zantac decision, I think one of the real problems that Judge
4 Rosenberg wrestled with in Zantac that we don't have here is
5 she found that the plaintiffs' experts I believe could not
6 reliably tell you how much was there actually in the pills
7 because of the way that the NDMA was formed at different times.
8 And she said if you can't figure that out, you can't go
9 anywhere, because you can't tell them how much it was. We
10 don't have that problem in this case.

11 In this case we have their testing showing massive,
12 hundreds of times the levels the FDA ultimately applied. And
13 at the time it was sold the level that was allowed was zero.
14 So it's a very different case.

15 And, look, we think that this case should go to trial
16 on all the claims. We think that we should go to trial. The
17 summary judgment motions and rulings said we can go to trial
18 with, which is the warranty claim can go forward. They can
19 make their argument on efficacy. The jury can let the
20 horserace be played and they can decide which horse wins or by
21 how much.

22 CHIEF JUDGE BUMB: Why shouldn't I try the personal
23 injury cases first?

24 MR. SLATER: Well, because we've had this litigation
25 going for over five years.

1 CHIEF JUDGE BUMB: Right.

2 MR. SLATER: We have no -- I will say, we have no
3 problem with getting the personal injury cases -- and we're
4 ready to have that conversation -- going and get onto a track
5 to get them prepared. But we need to start trying cases here.
6 We need to start to bring things to a head. And, look, if Your
7 Honor is --

8 CHIEF JUDGE BUMB: No one is working harder,
9 respectfully, to make that happen.

10 MR. SLATER: I know that, Judge. I was not
11 suggesting you weren't. You're just asking from our
12 perspective.

13 Maybe one way to handle it, if Your Honor decides
14 that the warranty claim is too problematic from your
15 perspective, you can always decide to try the other two claims.

16 CHIEF JUDGE BUMB: I'm not trying more trials than I
17 need to.

18 MR. SLATER: We're ready to go to trial in --

19 CHIEF JUDGE BUMB: I don't think you are. I don't
20 think the parties are. There is such a huge disconnect. I
21 don't even know how I do the jury charges.

22 MR. SLATER: That's --

23 CHIEF JUDGE BUMB: There's such a disconnect to me.
24 I'm going to go back, I'll take a look at the jury charges. I
25 want to confer with Judge Vanaskie.

1 But I -- I don't think you are.

2 MR. SLATER: Well, let me --

3 CHIEF JUDGE BUMB: I don't think -- there is such a
4 disconnect between the parties.

5 I mean, you folks can't even agree on the words
6 you're going to use to the jury. You can't even agree on the
7 fact that genotoxic really doesn't mean genotoxic.

8 MR. SLATER: We'll, we're not saying that.

9 CHIEF JUDGE BUMB: Well, I'm exaggerating a little
10 bit.

11 MR. SLATER: Look, Judge, respectfully, I think that
12 a lot of what's happening here is the defendants are not being
13 reasonable, and they're fighting over every single issue. I
14 think I've just heard when I was making some notes before, if I
15 misheard, I can be corrected, I think that they just argued
16 that their expert didn't concede that the cGMPs were violated
17 by ZHP and they want to make that a fact question. He conceded
18 it on the stand, Dr. Afnan. They want to now try the issue
19 that their only expert conceded?

20 CHIEF JUDGE BUMB: Well --

21 MR. SLATER: I mean, that's unreasonable. And I
22 think the Court is going to need to step in, and we have that
23 issue for the PTO. That's been -- their expert has conceded --

24 CHIEF JUDGE BUMB: Are you talking about Dr. Afnan?

25 MR. SLATER: Yeah. He conceded that they violated

1 cGMPs. He conceded he agrees with the FDA. But they still
2 want to try the issue of whether or not they violated cGMPs. I
3 mean, they won't agree to anything.

4 CHIEF JUDGE BUMB: Well, I do recall he made a
5 concession, but I thought that he wanted to explain his answer
6 or something like that. But, you know, I don't need to get
7 into that. I'm not going to -- look, I can't make them
8 stipulate to it.

9 MR. SLATER: I understand. Well, maybe what we have
10 to do is enter a directed verdict then, because when Judge
11 Kugler decided the summary judgment motions, their expert
12 hadn't changed his position and admitted that cGMPs were
13 violated when we moved for summary judgment on cGMPs. Now he's
14 conceded it. So they have no expert to dispute it.

15 CHIEF JUDGE BUMB: Didn't you ask him the question,
16 though, did the FDA find that the cGMPs had been violated?

17 MR. SLATER: What I said is -- well, first of all, he
18 said --

19 CHIEF JUDGE BUMB: Well, you know what, it doesn't
20 matter.

21 MR. SLATER: It doesn't. Look, I was using it as an
22 example for I think that you're being put in a situation where
23 the defendants are fighting on every single issue, and they're
24 not being reasonable, frankly, and that's why we can't agree on
25 things. And I was giving you that example which I just heard.

1 So that was the reason for that. I'm not trying to pull the
2 Court into a rabbit hole.

3 CHIEF JUDGE BUMB: Well, I'm going to give Judge
4 Vanaskie all the props that he deserves for handling all of
5 these issues.

6 I'll just circle back to where I kind of started,
7 which is, you know, the defendants very vigorously, when I was
8 assigned this case, argued that this is not the case to try
9 first. They had reasons there. I considered them. And I
10 thought that they were -- the problems that they discussed, I
11 thought that they were surmountable, and I thought that the
12 case could move forward.

13 But I have to admit, every time we get together, it
14 becomes -- I become less convinced that this is the right way
15 to proceed, because I just -- there's such a disconnect between
16 the parties.

17 I do think it's not been wasted time. I think we've
18 come a long way in funneling things and distilling things and
19 getting a better understanding of the case. So I would like to
20 believe that none of this time has been wasted. I think it's
21 been productive.

22 MR. SLATER: Judge, we're not going to be any more
23 agreeable if you shift to the personal injury cases. It's
24 going to be the same show.

25 CHIEF JUDGE BUMB: No. But I'm going to have clarity

1 and I'm going to have time and I'm going to lay out within four
2 corners of an opinion as to what's in, what's out, what the
3 claims are and what the claims aren't. And that will be our
4 roadmap.

5 Because right now, I don't know how to say this,
6 right now I think there's a lot of "this" going on. And --

7 MR. SLATER: Your Honor, if the issue is the warranty
8 claim, counsel just asked you to grant summary judgment on our
9 warranty claim, because that's where this issue comes in. It's
10 not an issue with the consumer protection or the fraud where
11 there's active misconduct. Your Honor said that before.

12 So you know what, let them make the motion. If Your
13 Honor thinks that our warranty claim should be bounced, you'll
14 dismiss it and we can try the other two claims and we'll have
15 our rights and we'll move forward. If you want to let it go
16 forward with -- I mean, I think that would be the wrong outcome
17 because we think that Judge Kugler was correct to say that the
18 value question is for the jury and that we're allowed to put
19 Dr. Conti on to say there was no value and here's why, based on
20 my assumptions. I think that should go forward like that.

21 If Your Honor wants to listen to their argument and
22 say you know what, you guys want general causation so badly and
23 you think that's what's needed to balance, then we have to try
24 general causation. They can't complain about it because they
25 asked for it over our objection.

1 So, you know --

2 CHIEF JUDGE BUMB: Right.

3 MR. SLATER: -- however it goes, I think that
4 we're -- we want to try this case. We have -- this litigation
5 has been going on for five years. At some point we need to
6 bring it to the point where we get to trials, because we're
7 never going to get to the end unless we have trials. And if
8 this trial gets put off and we go on to a new track, the
9 defendants are going to exhale, and that's going to be the end
10 of anything bringing us to any conclusion. And they're going
11 to say, great, we can bill for this thing for the next five
12 years while we try personal injury cases, and it will go on
13 forever, and the companies can hold their money in their bank
14 accounts and not worry about it because it's going to go on
15 forever.

16 And that's the practical reality of what it is.
17 That's why we want to get to trial.

18 COVID destroyed this litigation. It put us on such a
19 slow track. It's the reality. We had to deal with it. We
20 lost over two years. And it just -- it just -- it put a giant
21 crimp in it. But we want to try the case. And I think that
22 the suggestions I'm making which is, A, follow Judge Kugler's
23 decision, let us try the case, let them argue efficacy, let the
24 jury make the call. If you want to let in general causation,
25 we have to live with it, we'll try it. If you want to put

1 guardrails around that how much can come in, fine. Your Honor
2 has the right to do that.

3 I think you should give a limiting instruction. If
4 there's no general causation, you explain it. Even if there is
5 general causation, you explain how it factors in. If it
6 factors in on value but not on liability, then we live with it.
7 But we are ready to try this case.

8 Judge Vanaskie has been busting his butt -- I think I
9 can say that in the court -- on these designations. The
10 testimony is basically set for most of the witnesses in the
11 trial. We've done an enormous amount of work. We've already
12 gotten ready for trial now twice with a massive investment of
13 time and money. We're sitting here holding off hotels right
14 now because they want contracts signed and we're telling them
15 we're not signing anything because we're not sure what's
16 happening right now. We want to try this case. We want to go
17 to a verdict. We want to live with the outcome. And we want
18 to get it done.

19 And there's nothing about this -- I understand that
20 there's frustration that we're not agreeing. We're not going
21 to agree. This is high-stakes litigation with three of the
22 biggest law firms in the world, and they're not going to agree.
23 These are big companies overseas that don't seem to really
24 care. And they don't seem to care what they did. That's why
25 they're minimizing what they sold into this market. That's why

1 they keep saying "no harm, no foul." I mean, I'm just calling
2 it like it is. And we need to go to trial. We need to move
3 this, and that's why -- I'm not saying it's unreasonable to say
4 we got to get these personal injury cases going, too. We're
5 ready to do that. We're ready. We have bellwethers from years
6 ago that were picked.

7 And we have a way that we can present to Your Honor
8 in short term to say, look, on another track, let's get these
9 personal injury cases going. I'm dying to try a personal
10 injury case in this, especially with ZHP's massively
11 contaminated pills. Let's go. Let's do it. Let's start with
12 the liver -- they already think those cases have no value,
13 they're all garbage. Let's try the liver cancer cases. Let's
14 line them up and let's start trying them soon. We'll get
15 specific causation experts. We'll do what we need to do to
16 work them up, but we shouldn't put that ahead of this because
17 this gets thrown off after all the work we've done when there
18 is a way to try this case. And I think, Your Honor, we can
19 definitely do it. We've talked through this stuff.

20 I don't think any of this time has been wasted. We
21 have learned a lot about our case. Your Honor has learned a
22 lot. The defense has learned a lot just through this process.
23 I think a lot has been refined.

24 CHIEF JUDGE BUMB: Yeah. I don't think the time has
25 been wasted.

1 MR. SLATER: No.

2 CHIEF JUDGE BUMB: And I'm glad you agree with that,
3 but --

4 MR. SLATER: The testimony has been worked on. I
5 mean, we'd have to put a little more testimony back in or
6 whatever it is on general cause that we've pulled out. It's
7 not going to be a big deal. Judge Vanaskie is the fastest
8 decider in the West on this stuff.

9 But we adamantly don't want this case kicked. We
10 really need to go to trial. If you talk about maybe we need to
11 move it a month or so, nobody's going to cry about that because
12 that's life and it happens. But putting it off indefinitely
13 with all the work we've done, all the money we've spent, all
14 the time we've put into it, that would be very, very
15 prejudicial to us.

16 CHIEF JUDGE BUMB: It does seem, though, that the
17 case has been somewhat of a moving target. I think the parties
18 have to agree with that. I think that there has been a
19 fine-tuning of the case. I think that there has been greater
20 clarity that's been, you know, by just having these arguments,
21 I think. And so it hasn't been time that's been wasted.

22 And I'm certainly grateful that they're happening now
23 and not over, you know, all these sidebars while the jury sits
24 waiting.

25 Does anybody want to respond to what Mr. Slater is

1 proposing?

2 MS. ALLON: I -- I could start. So, I think there's
3 a problem with the warranty claim, as Mr. Ostfeld said.

4 If the proposal is we're going to put general cause
5 in the case, which is what I understand Mr. Slater to be
6 saying -- leaving aside the fact that right now he says he has
7 85 hours of video without general cause, so I don't even know
8 how long the trial would be with general cause, but let's leave
9 the timing aside.

10 Where I think we are is, he has one theory that is in
11 this case, and it is worthless, one word. That is the only
12 theory that survived the motion to dismiss. But more
13 importantly, it's the only theory that has any evidence, expert
14 evidence, assuming that some version of Dr. Conti is allowed in
15 by this Court.

16 And so in that version of the trial, he will argue
17 that the pills were worth zero because they cause cancer. And
18 the defendants will get to say, number one, they didn't cause
19 cancer.

20 Number two, they had therapeutic value.

21 And number three, had you not bought these pills, you
22 would have had to buy more expensive alternatives.

23 He cannot then come back and say to the jury, well,
24 if it's not zero, just pick a number. That would be diminution
25 in value. That's been dismissed by Judge Kugler, but he

1 doesn't have a witness, he doesn't have evidence of if it's not
2 zero, what is the value.

3 As Mr. Ostfeld said, he would have had to have done a
4 survey or other economic evidence that would have shown
5 diminution in value, and he didn't do that.

6 So if we're going to go all or nothing on
7 worthlessness, one word, then that's the confines of the trial.
8 So I don't think we can do it in four weeks, obviously. But
9 that is the confines.

10 In terms of personal injury versus economic loss, we
11 were always of the view that it made sense to start with
12 personal injury. In my experience in these cases, *Zantac* is a
13 good example, personal injury always goes first for this
14 reason. Judge Kugler disagreed. You know, this Court said it
15 didn't -- it wasn't originally going to revisit Judge Kugler's
16 ruling, so we find ourselves where we find ourselves. I don't
17 think any of us has changed our view that if we were on a clean
18 slate, we would start with personal injury, for all of the
19 reasons that we discussed this morning.

20 To your point, it just -- the issue of causation is
21 much more focused. It's the only thing you're dealing with.
22 You don't have any of these ancillary issues. We try the
23 personal injury case. So we would have been happy to do that,
24 and I think we are happy to do that. So the view of that has
25 not changed.

1 But if we're going to do economic loss, it has to be
2 with those clear confines. It cannot now become a
3 diminution-in-value case, because that would be a new case that
4 has a claim that was dismissed by Judge Kugler, but also has a
5 claim that has not been developed or tested through any
6 discovery.

7 MS. LOCKARD: Your Honor, on behalf of Teva, we would
8 agree with that. As Ms. Allon has said, we've always
9 maintained that the quickest, the best, the easiest path is the
10 personal injury case.

11 I agree that all the work we've done, including Judge
12 Vanaskie, thank you, can be applied to those PI cases. I think
13 I heard Mr. Slater say that the Court could grant directed
14 verdict on the express warranty claim. That goes up.
15 Meanwhile, we shift gears, we pivot, we get the PI case ready
16 to go.

17 CHIEF JUDGE BUMB: Well, no, I don't think he said
18 that. He said I could grant summary judgment, but then he
19 would appeal that. So why would I do that without
20 consideration? If he wants to dismiss his claim, that's a
21 different story.

22 MS. LOCKARD: Understood.

23 I think the same logic holds, though, with respect to
24 moving forward on the PI. We get general cause issues decided
25 by the jury. We get the meat of the liability decided by the

1 jury. I mean, not to hold out hope for settlement, but if
2 there is any way to move the parties closer together is to get
3 some resolution of some of these issues through a jury.

4 MS. DAVIDSON: Your Honor, I don't want to repeat
5 what the other two defendants just said, but obviously the
6 typical process in a mass tort is bellwether trials of personal
7 injury claims. We've obviously pleaded very hard for that. It
8 didn't happen. But we obviously agree that is a simpler,
9 clearer approach. This is a huge behemoth. There is also
10 clearly at this point not a reasonable way to try this in the
11 time allotted in November and, therefore, we would strongly
12 support pivoting to something that's actually doable and is not
13 sort of this -- this Frankenstein type of a situation.

14 CHIEF JUDGE BUMB: Okay.

15 I'm going to mull it over. I want to talk to Judge
16 Vanaskie. I want to think about it some more.

17 (Court conferring with Judge Vanaskie.)

18 JUDGE VANASKIE: I have a conference tomorrow.

19 CHIEF JUDGE BUMB: Yeah. So you'll hear from me by
20 the early evening.

21 Yeah.

22 MR. OSTFELD: Your Honor, on that point, Judge
23 Vanaskie very kindly gave us until 5:00 p.m. today for a
24 redline of the final pretrial order.

25 CHIEF JUDGE BUMB: Everything's on hold until I

1 decide.

2 MR. OSTFELD: Thank you, Your Honor.

3 CHIEF JUDGE BUMB: Right, Judge Vanaskie?

4 JUDGE VANASKIE: Yes.

5 CHIEF JUDGE BUMB: Yes.

6 MR. SLATER: That's fine. Because we have been
7 exchanging anyway.

8 CHIEF JUDGE BUMB: Just put everything on hold for
9 the next three or four hours. I have to think about this. I
10 want to think about it. I'll issue a text order; you'll know
11 where I stand, okay?

12 MR. SLATER: Thank you, Your Honor.

13 MS. ALLON: Thank you, Your Honor.

14 CHIEF JUDGE BUMB: Good to see you all. Thank you.

15 MR. OSTFELD: Thank you, Your Honor.

16 MS. DAVIDSON: Thank you, Your Honor.

17 MS. LOCKARD: Thank you, Your Honor.

18 THE COURTROOM DEPUTY: All rise.

19 (Proceedings concluded at 3:20 p.m.)

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21 **FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE**
22 -----

23 I certify that the foregoing is a correct transcript
24 from the record of proceedings in the above-entitled matter.
25

1 /S/John J. Kurz, RDR-RMR-CRR-CRC

October 11, 2024

2 Court Reporter/Transcriber

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<p>CHIEF JUDGE BUMB: [207] JUDGE VANASKIE: [3] 4/10 92/18 93/4 MR. HONIK: [1] 4/19 MR. NIGH: [1] 4/22 MR. OSTFELD: [30] 5/9 25/12 25/20 26/2 26/14 26/20 27/19 28/6 29/25 31/15 32/9 32/20 33/20 34/3 68/5 68/14 68/16 68/24 69/2 69/6 69/8 69/11 69/21 69/24 70/2 70/17 71/7 92/22 93/2 93/15 MR. SLATER: [158] MS. ALLON: [13] 4/8 5/4 31/13 31/16 31/20 31/23 31/25 32/5 35/5 35/15 35/19 89/2 93/13 MS. BRANCATO: [1] 5/7 MS. DAVIDSON: [4] 5/13 36/5 92/4 93/16 MS. LOCKARD: [10] 4/9 5/11 60/1 60/19 60/21 63/6 63/15 91/7 91/22 93/17 MS. 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